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भारतीय मानक

चिकित्सा गैस पाइपलाईन प्रणालियाँ

भाग 1 संपीड़ित चिकित्सा गैस और निर्वात के लिए पाइपलाईन प्रणालियाँ

Indian Standard

MEDICAL GAS PIPELINE SYSTEMS

PART 1 PIPELINE SYSTEMS FOR COMPRESSED MEDICAL GASES AND VACUUM

ICS 11.040.10

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3.3
branch
portion of the pipeline distribution system which supplies one or more areas on the same floor of the facility

3.4
commissioning
proof of function to verify that the agreed system specification is met and is accepted by the user or his representative

3.5
control equipment
items necessary to maintain the medical gas pipeline system within the specified operating parameters

NOTE Examples of control equipment are pressure regulators, pressure-relief valves, alarms, sensors, manual or automatic valves and non-return valves.

3.6
cryogenic liquid system
supply system containing a gas stored in the liquid state in a vessel at temperatures lower than −150 °C

3.7
cylinder bundle
pack or pallet of cylinders linked together with one or more connectors for filling and emptying

3.8
diversity factor
factor which represents the maximum proportion of terminal units in a defined clinical area which will be used at the same time, at flowrates defined in agreement with the management of the healthcare facility

3.9
double-stage pipeline distribution system
pipeline distribution system in which gas is initially distributed from the supply system at a pressure higher than the nominal distribution pressure, and is then reduced to the nominal distribution pressure by line pressure regulator(s)

NOTE This initial higher pressure is the nominal supply system pressure (see 3.32).

3.10
emergency clinical alarm
alarm to indicate to medical and technical staff that there is abnormal pressure within a pipeline that requires an immediate response

3.11
emergency inlet point
inlet point which allows the connection of an emergency supply

3.12
emergency operating alarm
alarm to indicate to technical staff that there is abnormal pressure within a pipeline that requires an immediate response

3.13
emergency supply
source of supply intended to be connected to an emergency inlet point

3.14
gas-specific
having characteristics which prevent connections between different gas services

3.15

gas-specific connector

connector with dimensional characteristics which prevent connections between different gas services

NOTE Examples of gas-specific connectors are quick connectors, screw-threaded connectors, diameter-indexed safety system (DISS) connectors or non-interchangeable screw-threaded (NIST) connectors.

3.16

high-dependency patient

patient with a continual need of a medical gas/vacuum supply, who will be adversely affected by a medical gas/vacuum supply failure to such a degree that his/her clinical condition or his/her safety can be compromised

3.17

information signal

visual indication of normal status

3.18

line pressure regulator

pressure regulator intended to supply the nominal distribution pressure to the terminal units

3.19

low-pressure hose assembly

assembly consisting of a flexible hose with permanently attached gas-specific inlet and outlet connectors and designed to conduct a medical gas at pressures less than 1 400 kPa

3.20

main line

portion of the pipeline distribution system connecting the supply system to risers and/or branches

3.21

maintenance supply assembly

inlet point which allows the connection of a maintenance supply

3.22

maintenance supply

source of supply intended to supply the system during maintenance

3.23

manifold

device for connecting the outlet(s) of one or more cylinders or cylinder bundles of the same gas to the pipeline system

3.24

manifold pressure regulator

pressure regulator intended to be installed within sources of supply containing cylinders or cylinder bundles

3.25

manufacturer

natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

3.26

maximum distribution pressure

pressure at any terminal unit when the pipeline system is operating at zero flow

Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHR 11

NATIONAL FOREWORD

This Indian Standard (Part 1) which is identical with ISO 7396-1 : 2007 'Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Anaesthetic, Resuscitation and Allied Equipment Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

Many healthcare facilities use pipeline systems to deliver medical gases and to provide vacuum to areas where they are used in patient care or to power equipment such as ventilators and surgical tools.

This standard specifies requirements for pipeline systems for compressed medical gases, gases for driving surgical tools and yacuum. It is intended for use by those persons involved in the design, construction, inspection and operation of healthcare facilities treating human beings. Those persons involved in the design, manufacture and testing of equipment intended to be connected to pipeline systems should also be aware of the contents of this standard.

This standard seeks to ensure that medical gas pipelines contain only the specific gas (or vacuum) intended to be supplied. For this reason, gas-specific components are used for terminal units and for other connectors which are intended to be used by the operator. In addition, each system is tested and certified to contain only the specific gas (or vacuum).

The objectives of this standard are to ensure the following:

a) Non-interchangeability between different pipeline systems by design,

b) Continuous supply of gases and vacuum a specified pressures by providing appropriate sources,

c) Use of suitable materials,

d) Cleanliness of components,

e) Correct installation,

f) Provision of monitoring and alarm systems,

g) Correct marking of the pipeline system,

h) Testing, commissioning and certification,

j) Purity of the gases delivered by the pipeline system, and

k) Correct operational management.

This standard is published in two parts. The other part of this series is:

Part 2 Anaesthetic gas scavenging disposal systems

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker in the International Standard while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to the following International Standard for which Indian Standard also exists. The corresponding Indian Standard which is to be substituted in its place is listed below along with its degree of equivalence for the edition indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 15001 : 2003 Anaesthetic and respiratory equipment — Compatibility with oxygen	IS/ISO 15001 : 2003 Anaesthetic and respiratory equipment — Compatibility with oxygen	Identical

The technical committee responsible for the preparation of this standard has reviewed the provisions of the following International Standards and has decided that they are acceptable for use in conjunction with this standard:

International Standard	*Title*
ISO 3746 : 1995	Acoustics — Determination of sound power levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane
ISO 5359 : 2008	Low-pressure hose assemblies for use with medical gases
ISO 8573-1 : 2001	Compressed air — Part 1: Contaminants and purity classes
ISO 9170-1 : 2008	Terminal units for medical gas pipeline systems — Part 1:Terminal units for use with compressed medical gases and vacuum
ISO 10083 : 2006	Oxygen concentrators for use with medical gas pipeline systems
ISO 10524-2 : 2005	Pressure regulator for use with medical gases — Part 2: Manifold and line pressure regulators
ISO 11197 : 2004	Medical supply units
ISO 14971 : 2007	Medical devices — Application of risk management to medical devices
ISO 21969 : 2005	High-pressure flexible connections for use with medical gas systems
IEC 60601-1-8 : 2006	Medical electrical equipment — Part 1-8: General requirements for safety — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN 286-1 : 1998	Simple unfired pressure vessels designed to contain air or nitrogen — Part 1: Pressure vessels for general purposes
EN 1041 : 2008	Information supplied by the manufacturer with medical devices
EN 13348 : 2008	Copper and copper alloys — Seamless round copper tubes for medical gases or vacuum

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

3.27

medical air

natural or synthetic mixture of gases, mainly composed of oxygen and nitrogen in specified proportions, with defined limits for the concentration of contaminants, supplied by a medical gas pipeline system and intended for administration to patients

NOTE 1 Medical air can be produced by supply systems with air compressors or by supply systems with proportioning units.

NOTE 2 Medical air produced by air compressor systems is called "medicinal air" by European Pharmacopoeia 2005.

NOTE 3 Medical air produced by proportioning systems is called "synthetic medicinal air" by European Pharmacopoeia 2005.

3.28

medical gas

any gas or mixture of gases intended for administration to patients for anaesthetic, therapeutic, diagnostic or prophylactic purposes

3.29

medical gas pipeline system

complete system which comprises a supply system, a monitoring and alarm system and a distribution system with terminal units at the points where medical gases or vacuum are required

3.30

minimum distribution pressure

lowest pressure occurring at any terminal unit when the pipeline system is operating at the system design flow

3.31

nominal distribution pressure

pressure which the medical gas pipeline system is intended to deliver at the terminal units

3.32

nominal supply system pressure

pressure which the supply system is intended to deliver at the inlet to the line pressure regulators

3.33

non-cryogenic liquid system

supply system containing a gas stored under pressure in the liquid state in a vessel at temperatures not lower than −50 °C

3.34

non-return valve

valve which permits flow in one direction only

3.35

operating alarm

alarm to indicate to technical staff that it is necessary to replenish the gas supply or to correct a malfunction

3.36

oxygen concentrator

device which produces oxygen-enriched air from ambient air by extraction of nitrogen

3.37

oxygen-enriched air

gas produced by an oxygen concentrator

3.38

pipeline distribution system

portion of a medical gas or vacuum pipeline system linking the sources of supply of the supply system to the terminal units

3.39

pressure regulator

device which reduces the inlet pressure and maintains the set outlet pressure within specified limits

3.40

pressure-relief valve

device intended to relieve excess pressure at a preset pressure value

3.41

primary source of supply

portion of the supply system which supplies the pipeline distribution system

3.42

proportioning unit

device in which gases are mixed in a specified ratio

3.43

reserve source of supply

that portion of the supply system which supplies the complete, or a portion(s) of the, pipeline distribution system in the event of failure or exhaustion of both the primary and secondary sources of supply

3.44

riser

portion of the pipeline distribution system traversing one or more floors and connecting the main line with branch lines on various levels

3.45

secondary source of supply

portion of the supply system which supplies the pipeline distribution system in the event of exhaustion or failure of the primary source of supply

3.46

shut-off valve

valve which prevents flow in both directions when closed

3.47

silencing

temporary stopping of an auditory alarm signal by manual action

NOTE This is also referred to as audio pausing.

3.48

single fault condition

condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present

NOTE Maintenance of equipment is considered a normal condition.

3.49

single-stage pipeline distribution system

pipeline distribution system in which gas is distributed from the supply system at the nominal distribution pressure

3.50

source of supply

portion of the supply system with associated control equipment which supplies the pipeline distribution system

5.4 Supply systems with mobile or stationary cryogenic or non-cryogenic vessels

NOTE Regional or national regulations applying to mobile and stationary cryogenic and non-cryogenic vessels can exist.

5.4.1 Except for nitrogen for driving surgical tools, a supply system with stationary cryogenic or non-cryogenic vessels shall consist of one of the following:

a) one stationary cryogenic or non-cryogenic vessel with associated equipment and two banks of cylinders or cylinder bundles;

b) two stationary cryogenic or non-cryogenic vessels with associated equipment and one bank of cylinders or cylinder bundles;

c) three stationary cryogenic or non-cryogenic vessels with associated equipment.

The sources-of-supply management procedure (see Annex G) should take into account the natural vaporization of liquid contained in cryogenic and non-cryogenic vessels.

5.4.2 All supply systems with mobile or stationary cryogenic or non-cryogenic vessels shall comply with 5.2.2.1.

5.5 Supply systems for air

5.5.1 General requirements

5.5.1.1 A supply system for medical air or air for driving surgical tools shall be one of the following:

a) a supply system with cylinders or cylinder bundles as specified in 5.3;

b) a supply system with air compressor(s) as specified in 5.5.2;

[redacted]

5.5.2 Supply systems with air compressor(s)

5.5.2.1 (*) Regional or national regulations applying to medical air produced by a supply system with air compressor(s) can exist. Where such regulations do not exist, medical air shall comply with the following:

a) oxygen concentration	$\geqslant$ 20,4 % (volume fraction) and $\leqslant$ 21,4 % (volume fraction)
b) total oil concentration	$\leqslant$ 0,1 mg/m^3 measured at ambient pressure
c) carbon monoxide concentration	$\leqslant$ 5 ml/m^3
d) carbon dioxide concentration	$\leqslant$ 500 ml/m^3
e) water vapour content	$\leqslant$ 67 ml/m^3
f) sulfur dioxide concentration	$\leqslant$ 1 ml/m^3
g) $NO + NO_2$ concentration	$\leqslant$ 2 ml/m^3

NOTE 1 Oil can be present as liquid, aerosol and vapour.

NOTE 2 These values are taken from the European Pharmacopoeia 2005.

5.5.2.2 Medical air and air for driving surgical tools supplied by compressor systems shall be filtered to maintain the particulate contamination below the level provided by Table 2, class 2 of ISO 8573-1:2001.

NOTE Regional or national requirements applying to particulate contamination can exist.

5.5.2.3 (*) Regional or national regulations applying to air for driving surgical tools produced by a supply system with air compressor(s) can exist. Where such regulations do not exist, air for driving surgical tools shall comply with the following:

a) total oil concentration	$\leqslant$ 0,1 mg/m^3 measured at ambient pressure
b) water vapour content	$\leqslant$ 67 ml/m^3

NOTE 1 Oil can be present as liquid, aerosol and vapour.

NOTE 2 For air for driving surgical tools, a low water content is necessary to prevent the formation of water or ice (from cooling due to adiabatic expansion) which can damage tools.

5.5.2.4 A supply system with compressor(s) for medical air shall comprise at least three sources of supply, at least one of which shall be a compressor unit. The supply system shall be such that the system design flow can be supplied with any two sources of supply out of service.

The source of supply shall be one of the following:

a) a compressor unit;

b) a bank of cylinders or cylinder bundles.

The compressor unit(s) shall be provided with receiver(s) and conditioning unit(s), as required.

If a supply system includes two or more sources of supply fed from compressor units, at least two conditioning units shall be provided.

Where the medical air supply system consists of three or more compressor units, which can be switched between the different sources of supply to provide adequate capacity, these shall be arranged so that during maintenance on any compressor unit or system component and during a subsequent single fault condition on any component of the system (e.g. control system), the remaining compressor units and components shall be capable of supplying the system design flow to ensure continuity of supply.

5.2.2.2 Control equipment shall be designed so that components can be maintained without interrupting the gas supply.

5.2.3 Primary source of supply

The primary source of supply shall be permanently connected and shall be the main source of supply to the medical gas pipeline.

5.2.4 Secondary source of supply

The secondary source of supply shall be permanently connected and shall automatically supply the pipeline in the event that the primary source of supply is unable to supply the pipeline.

5.2.5 Reserve source of supply

The reserve source of supply shall be permanently connected. Activation of the reserve supply in the event of both the primary and the secondary sources of supply being unable to supply the pipeline or for maintenance can be automatic or manual. A reserve source of supply can also be required for air or nitrogen for driving surgical tools.

The manufacturer together with the healthcare facility management shall determine the location of the reserve source(s) of supply to cover the complete pipeline system.

NOTE This can result in a number of reserve sources of supply, some or all of which could be close to the terminal units.

5.2.6 Means of pressure relief

5.2.6.1 For all compressed medical gases except air, pressure-relief valves shall be vented to the outside of the building and the vents shall be provided with means to prevent the ingress of, for example, insects, debris and water. The vents shall be located remote from any air intakes, doors, windows or other openings in buildings. Consideration shall be given to the potential effects of prevailing winds on the location of the vents.

5.2.6.2 All pressure-relief valves shall close automatically when excess pressure has been released.

5.2.6.3 It shall not be possible to isolate a means of pressure relief, for example by a shut-off valve, from the pipeline or the pressure regulator to which it is connected. If a valve or a flow-limiting device is incorporated for maintenance, it shall be fully opened by the insertion of the means of pressure relief.

NOTE Attention is drawn to regional, national and international standards for pressure-relief valves, e.g. ISO 4126-1 [1].

5.2.6.4 Means shall be provided to protect the pressure-relief valve from tampering.

5.2.6.5 Any portion of a pipeline within a supply system where gas in liquid phase can be entrapped between two shut-off valves shall be provided with means to relieve excess pressure resulting from vaporization of the liquid

5.2.7.2 The maintenance supply assembly shall have a gas-specific inlet connector, a means of pressure relief, a non-return valve and a shut-off valve. The design of the supply assembly shall take into account the flow which can be required under maintenance conditions. The supply assembly shall be physically protected to prevent tampering and unauthorized access.

The maintenance supply assembly should be located outside of the area of the supply system and should allow access by vehicles.

5.2.8 Pressure regulators

For single-stage pipeline distribution systems, the pressure regulators within the supply systems shall be capable of controlling pipeline pressure at levels which meet the requirements specified in Table 2, 7.2.2 and 7.2.3.

5.3 Supply systems with cylinders or cylinder bundles

5.3.1 A supply system with cylinders or cylinder bundles shall comprise:

a) a primary source of supply which supplies the pipeline;

b) a secondary source of supply which shall automatically supply the pipeline when the primary source of supply becomes exhausted or fails;

c) a reserve source of supply (except for air or nitrogen for driving surgical tools).

Except for air and nitrogen for driving surgical tools, the supply system with cylinders or cylinder bundles shall be such that the system design flow can be supplied with any two sources of supply out of service.

5.3.2 The primary and secondary sources of supply which alternately supply the pipeline shall each consist of one bank of cylinders or cylinder bundles. When an exhausted bank of cylinders or cylinder bundles is replaced, it shall be possible to reset the automatic change-over either manually or automatically. Each bank shall have its cylinders or cylinder bundles connected to a manifold with its own pressure regulator. Except for air, vent valves, if fitted on manifolds, shall be vented outside of the building.

5.3.3 Except for banks with only one cylinder or cylinder bundle, a non-return valve shall be installed at the manifold end of each flexible connection between the cylinder or cylinder bundle and the manifold.

5.3.4 A filter having a pore size no greater than 100 µm shall be provided between the cylinder(s) and the first pressure regulator.

5.3.5 (*) The flexible connections between each cylinder or cylinder bundle and the manifold shall comply with ISO 21969. Non-metallic (polymer-lined or rubber-reinforced) flexible hoses shall not be used.

5.3.6 Means shall be provided to individually secure all cylinders located within the supply system to prevent them from falling over. The flexible connections between each cylinder and the manifold shall not be used for this purpose.

5.3.7 All supply systems with cylinders shall comply with 5.2.2.1.

5.9 Location of cylinder manifolds

The location of cylinder manifolds shall be defined in collaboration with the relevant authorities and in accordance with the relevant national standards. Informative guidelines are given in Annex B.

5.10 Location of stationary cryogenic vessels

The location of stationary cryogenic vessels shall be defined in collaboration with the relevant authorities and the gas supplier and in accordance with the relevant national standards. Informative guidelines are given in Annex B.

6 Monitoring and alarm systems

6.1 General

Monitoring and alarm systems have four different purposes which are fulfilled by operating alarms, emergency operating alarms, emergency clinical alarms and information signals. The purpose of operating alarms is to notify the technical staff that one or more sources of supply within a supply system are no longer available for use and it is essential that action be taken. Emergency operating alarms indicate abnormal pressure within a pipeline and could require immediate response by the technical staff. Emergency clinical alarms indicate abnormal pressure within a pipeline and could require immediate response by both the technical and the clinical staff. The purpose of information signals is to indicate normal status.

6.2 Installation requirements

6.2.1 If not specified in this part of ISO 7396, the location of indicator panels shall be determined by the system manufacturer in consultation with the healthcare facility management using risk management principles.

6.2.2 Monitoring and alarm systems shall comply with the following requirements:

a) the design and location of the indicator panels shall allow continuous observation;

b) an indicator panel displaying all operating alarm signals specified in 6.4 shall be installed in at least one location allowing continual observation or communication;

c) the indicator panel(s) for the emergency clinical alarm signals specified in 6.5 shall be installed in the clinical and critical areas and an additional panel can be installed near the area shut-off valve and shall indicate the area monitored;

d) pressure gauges or indicators, if provided, shall show the distribution pressure and shall be marked to indicate the service and the area monitored;

e) visual indicators shall be provided for each condition monitored and shall be marked according to function;

f) the sensing devices for emergency clinical alarms listed in 6.5 shall be located downstream of each area shut-off valve;

g) means shall be provided for testing the activation mechanism and functioning of visual and auditory alarm signals;

h) it shall not be possible to isolate a pressure-sensing device, for example by a manually operated shut-off valve, while it is connected to the pipeline. If a valve is incorporated for maintenance purposes, it shall be opened by the insertion of the sensing device;

i) the operating tolerance on the set point of any pressure-sensing device shall not exceed ± 4 %.

6.2.3 (*) Monitoring and alarm systems shall be connected to both the normal and the emergency electrical power supplies and shall be individually electrically protected.

6.2.4 Alarm systems shall be designed so that an alarm is initiated if there is electrical failure between the sensor and the indicator.

6.3 Monitoring and alarm signals

6.3.1 General

The categories and the characteristics of the monitoring and alarm signals shall comply with Table 1.

6.3.2 Auditory signals

6.3.2.1 If a pattern of more than two tones or frequencies is used as an auditory signal, the auditory signal(s) for emergency clinical alarms shall conform to the requirements of IEC 60601-1-8.

6.3.2.2 All other auditory signals shall comprise one or two tones modulated equally, e.g. at a rate of 4 Hz between two tones of 440 Hz and 880 Hz. The A-weighted sound pressure level of the auditory components of these alarm signals at minimum volume shall be at least 2 dB above a white background level of 55 dB when tested in accordance with ISO 3746.

6.3.2.3 If an auditory signal can be silenced by the operator, the silencing shall not prevent the auditory signal from being activated by a new alarm condition.

6.3.2.4 (*) If an emergency auditory signal can be silenced by the operator, the period of silencing shall not exceed 15 min.

6.3.2.5 If means to allow permanent audio pausing of the auditory signal are provided, such means shall only be accessible to authorized staff.

6.3.3 Visual signals

6.3.3.1 The visual signals for emergency clinical alarms shall conform to the requirements of IEC 60601-1-8.

6.3.3.2 The indicator colours and the characteristics of visual signals shall comply with Table 1.

6.3.3.3 Visual indications should be perceived correctly and discriminated between under the following conditions (see IEC 60601-1-8):

a) operator with a visual acuity of 1 (corrected if necessary);

b) viewpoint at a distance of 4 m and at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of display of the visual indication;

c) under an ambient illuminance throughout the range of 100 lx to 1 500 lx.

6.3.4 Emergency and operating alarm characteristics

6.3.4.1 For emergency clinical alarms and emergency operating alarms (see Table 1), there shall be a visual and a simultaneous auditory signal.

6.3.4.2 For operating alarms (see Table 1), there shall be at least a visual signal.

6.3.4.3 When the condition which has caused the alarm has cleared, the auditory signal and the visual signal shall reset automatically or by deliberate operator action.

Table 1 — Alarm categories and signal characteristics

Category	Operator response	Indicator colour	Visual signal	Auditory signal
Emergency clinical alarm	Immediate response to deal with a hazardous situation	Complying with IEC 60601-1-8	Complying with IEC 60601-1-8	Complying with IEC 60601-1-8 [a]
Emergency operating alarm	Immediate response to deal with a hazardous situation	Red	Flashing [b]	Yes
Operating alarm	Prompt response to a hazardous situation	Yellow	Flashing [b]	Optional
Information signal	Awareness of normal status	Not red Not yellow	Constant	No

[a] If a pattern of more than two tones or frequencies is used.

[b] Visual flashing frequencies for operating alarms and emergency operating alarms should be between 0,4 Hz and 2,8 Hz with a duty cycle between 20 % and 60 %.

6.3.5 Information signals

Information signals shall be provided to indicate normal status and shall consist of a visual signal (see Table 1).

6.3.6 Remote alarm extensions

If a remote alarm extension is provided, it shall be arranged so that a failure in the external circuit will not affect the correct functioning of the main alarm. The location of indicator panels for a remote alarm shall be determined by the system manufacturer in consultation with the healthcare facility management using risk management principles.

6.4 Provision of operating alarms

Operating alarm signals shall be provided to indicate the following:

a) change-over from primary to secondary cylinder supplies, if different from 6.4 b);

b) any primary, secondary or reserve cylinder supply below minimum pressure or content;

NOTE For nitrous oxide and carbon dioxide cylinders, pressure might not indicate the content.

c) pressure in any cryogenic vessel below the minimum specified by the management of the healthcare facility in consultation with the gas supplier;

d) liquid level in any cryogenic vessel below the minimum specified by the management of the healthcare facility in consultation with the gas supplier;

e) malfunctioning of an air compressor system;

f) for air supplied by a compressor system, water vapour content above the level specified in 5.5.2.1 or 5.5.2.3;

g) malfunctioning of a proportioning system;

h) malfunctioning of a cryogenic system;

i) malfunctioning of a vacuum system;

j) malfunctioning of a supply system for oxygen-enriched air.

6.5 Provision of emergency clinical alarms

Emergency clinical alarm signals shall be provided to indicate the following:

a) deviation of the pipeline pressure downstream of any area shut-off valve by more than ± 20 % from the nominal distribution pressure;

b) an increase of pipeline pressure for vacuum upstream of any area shut-off valve above 66 kPa absolute.

6.6 (*) Provision of emergency operating alarms

Emergency operating alarm signals shall be provided to indicate the following:

a) for a single-stage distribution system, deviation of the pipeline pressure downstream of the main shut-off valve by more than ± 20 % from the nominal distribution pressure;

b) for a double-stage distribution system, deviation of the pipeline pressure downstream of the main shut-off valve by more than ± 20 % from the nominal supply system pressure;

c) increase of pipeline pressure for vacuum upstream (except for rings) of the main shut-off valve above 44 kPa absolute.

NOTE Regional or national regulations/standards can require a different value for the vacuum alarm.

The location of the pressure sensors should be consistent with the location and the intended use of ring shut-off valves, if fitted.

7 Pipeline distribution systems

7.1 Mechanical resistance

All sections of pipeline distribution systems for compressed medical gases shall withstand a pressure of 1,2 times the maximum pressure which can be applied to that section in single fault condition.

7.2 Distribution pressure

NOTE Unless otherwise specified, pressures in this part of ISO 7396 are expressed as gauge pressure (i.e. atmospheric pressure is defined as 0).

7.2.1 The nominal distribution pressure shall be within the ranges given in Table 2. Different gases can be delivered at different nominal distribution pressures in the same healthcare facility. For example, nitrous oxide can be delivered at a nominal distribution pressure lower than that for oxygen in order to prevent flow of nitrous oxide into the oxygen pipeline when gas mixers or other equipment are used.

Table 2 — Ranges of nominal distribution pressure

Pressure in kilopascals

Compressed medical gases other than air or nitrogen for driving surgical tools	400^{+100}_{0}
Air or nitrogen for driving surgical tools	800^{+200}_{-100} [a]
Vacuum	$\leqslant 60$ [b]

[a] Regional or national regulations/standards can require a different range.

[b] Absolute pressure.

10 Marking and colour coding

10.1 Marking

10.1.1 Pipelines shall be marked in accordance with 10.1.2 with the gas name and/or symbol adjacent to shut-off valves, at junctions and changes of direction, before and after walls and partitions, etc., at intervals of no more than 10 m and adjacent to terminal units.

NOTE 1 Typical examples of marking methods are metal tags, stencilling, stamping and adhesive markers.

NOTE 2 For identification of shut-off valves, see 8.1.3.

10.1.2 Marking shall

a) be in accordance with ISO 5359,

b) use letters not less than 6 mm high,

c) be applied with the gas name and/or symbol along the longitudinal axis of the pipeline, and

d) include arrows denoting direction of flow.

NOTE Regional or national regulations applying to marking of pipeline systems and their components can exist.

10.2 Colour coding

If colour coding is used for pipelines, it shall comply with ISO 5359.

NOTE 1 The colours specified in ISO 5359 and national standards are also used for non-medical applications.

NOTE 2 Regional or national regulations applying to colour coding of pipeline systems and their components can exist.

11 Pipeline installation

11.1 General

11.1.1 Pipeline systems shall be used only for patient care. No connections shall be made to a pipeline system for other uses. Permitted uses of medical air and air for driving surgical tools related to patient care are given in 5.5.1.2. Non-permitted uses of medical air and air for driving surgical tools are given in 5.5.1.3.

11.1.2 Pipelines and electrical services shall either

a) run in separate compartments, or

b) be separated by more than 50 mm.

NOTE Regional or national regulations which apply to electrical installations in buildings can exist.

11.1.3 The pipeline shall be bonded to an earth terminal as near as possible to the point at which the pipeline enters the building. The pipelines shall not themselves be used for earthing electric

11.1.5 Unprotected pipelines shall not be installed in areas of special hazard, e.g. in areas where flammable materials are stored. Where installation of pipelines in such a location is unavoidable, the pipeline shall be installed in an enclosure that will prevent the liberation of medical gas within the area should a leak occur.

NOTE Regional or national regulations which apply to building requirements and fire prevention can exist.

11.1.6 If pipelines are placed underground, they shall be placed in tunnels or ducts. The tunnel or duct shall be provided with adequate drainage to prevent the accumulation of water. If pipelines are placed in a tunnel or duct alone, with other services or with pipelines for other fluids or gases, the potential hazard arising from this situation shall be assessed using risk analysis procedures in accordance with ISO 14971. The risk assessment shall take into account that a leak which is not detected (e.g. by an alarm or periodic inspection) shall be considered a normal condition and not a single fault condition. The route of pipes placed underground should be indicated at the site by appropriate means, e.g. by continuous marking tape above the pipeline at approximately one-half the depth of burial.

11.1.7 Pipelines shall not be installed in elevator shafts.

11.1.8 A shut-off valve shall not be installed where a leak is likely to cause an accumulation of gas, for example in a sealed cavity.

11.1.9 Damage due to contact with corrosive materials shall be minimized, e.g. by the use of impermeable non-metallic materials applied to the outer surface of the pipes in the area where the contact can occur.

11.1.10 Allowance shall be made for expansion and contraction of pipelines.

11.1.11 All pipelines for medical gases shall be routed in such a way that they are not exposed to a temperature less than 5 °C above the dew point of the gas at pipeline pressure.

Attention is drawn to the possibility of restriction of flow due to exposure of vacuum pipeline to low temperature.

11.1.12 Pipeline components which come into contact with the medical gas shall be protected from contamination during installation.

11.2 Pipeline supports

11.2.1 Pipelines shall be supported at intervals to prevent sagging or distortion. Maximum intervals between supports for metallic and non-metallic pipes should not exceed the values given in Table 3.

NOTE Regional or national regulations specifying intervals between supports can exist.

11.2.2 The supports shall ensure that the pipeline cannot be displaced accidentally from its position.

11.2.3 The supports shall be of corrosion-resistant material, or shall be treated to prevent corrosion. Means shall be provided to prevent electrolytic corrosion between the pipes and the contacting surfaces of the supports.

11.2.4 Where pipelines cross electric cables, the pipelines shall be supported adjacent to the cables.

11.2.5 Pipelines shall not be used as support for, nor shall they be supported by, other pipelines or conduits.

Table 3 — Maximum intervals between supports for pipes

Pipe outside diameter mm	Maximum interval between supports m
Up to 15	1,5
22 to 28	2,0
35 to 54	2,5
54	3,0

11.3 Pipeline joints

11.3.1 Except for mechanical joints used for certain components, all metallic pipeline joints shall be brazed or welded. The methods used for brazing or welding shall permit the joints to maintain their mechanical characteristics up to an ambient temperature of 600 °C. Filler metals for brazing shall be nominally cadmium-free (i.e. less than 0,025 % mass fraction cadmium).

NOTE Mechanical joints (e.g. flanged or threaded connections) can be used to connect components such as shut-off valves, terminal units, pressure regulators, controls and monitoring and alarm sensors to the pipeline.

11.3.2 During brazing or welding of pipeline joints, the interior of the pipeline shall be continuously purged with shield gas.

NOTE EN 13133 [21] specifies requirements for the brazing process, test conditions, assessment and certificate. EN 13134 [22] specifies general rules (test procedures, test pieces) for the specification and approval of brazing procedures for all materials.

11.4 Extensions and modifications of existing pipeline systems

11.4.1 The components used in extensions and modification of an existing pipeline system shall comply with the relevant requirements of this part of ISO 7396.

11.4.2 The final connection of extensions shall be undertaken on only one system at a time, in order to minimize the risk of cross-connections. All other systems shall remain at nominal distribution pressure. Careful consideration shall be given to the location of this connection to minimize problems of access during installation and testing.

11.4.3 If an extension to an existing system is to be made upstream (downstream for vacuum) of an area shut-off valve, a shut-off valve shall be added at the connection point.

11.4.4 Extensions to an existing system shall not be made unless it can be demonstrated that the existing system meets the requirement specified in 12.6.10.

11.4.5 All terminal units in an extension shall be temporarily labelled to indicate that they are not to be used.

11.4.6 Connection should be made to the existing system only after the appropriate tests specified in Clause 12 have been successfully completed on the modification. The shut-off valve specified in 11.4.3 shall then be opened and further relevant tests completed on the modification.

11.4.7 When a connection is made to an existing system which is in use, that connection shall be made at a single brazed connection point which can be tested for leakage at nominal distribution pressure using leak-detection fluid.

11.4.8 When the modification has been completed and tested in accordance with Clause 12, all labels specified in 11.4.5 shall be removed.

11.4.9 The extension of an existing system shall be separated from the existing pipeline system during installation and pressure testing. A single shut-off valve between the two systems is not considered to be a safe separation.

12 Testing, commissioning and certification

12.1 General

Tests after completion of installation shall be carried out, documented and certified by the manufacturer.

NOTE Regional or national regulations requiring the manufacturer to have an approved quality system can exist.

An example of a procedure for testing and commissioning is given in Annex C.

12.2 General requirements for tests

12.2.1 Except for those tests in which the gas is specified, purging and testing as described in 12.4 shall be carried out with nitrogen, medical air or the specific gas. Medical air should be used for oxygen, oxygen/nitrous oxide mixture, oxygen-enriched air and air pipelines.

12.2.2 Before any testing according to 12.4 is carried out, every terminal unit in a system under test shall be labelled to indicate that the system is under test and the terminal unit shall not be used.

12.2.3 The resolution and the accuracy of all measuring devices used for testing shall be appropriate for the values to be measured.

12.2.4 All measuring devices used for certification shall be calibrated at appropriate intervals.

12.2.5 For extensions and modifications of existing pipeline distribution systems, not all the tests listed in 12.3 and 12.4 need to be carried out. The manufacturer shall specify and document which tests shall be carried out.

12.2.6 When the results of a test do not meet the pass criteria, remedial work shall be carried out and previous tests repeated as necessary.

12.3 Inspections and checks before concealment

The following inspections and checks shall be carried out:

a) inspections of marking and pipeline supports (see 12.5.1);

b) checks for compliance with design specifications (see 12.5.2).

NOTE Some tests for leakage and mechanical integrity can also be carried out before concealment (see 12.6.1).

12.4 Tests, checks and procedures before use of the system

The following tests and procedures shall be carried out in any order:

a) tests for leakage and mechanical integrity (see 12.6.1);

b) tests of area shut-off valves for leakage and closure and checks for correct zoning and correct identification (see 12.6.2);

c) test for cross-connection (see 12.6.3);

d) test for obstruction and flow (see 12.6.4);

e) checks of terminal units and NIST or DISS connectors for mechanical function, gas specificity and identification (see 12.6.5);

f) tests or checks of system performance (see 12.6.6);

g) tests of pressure-relief valves (see 12.6.7);

h) tests of all sources of supply (see 12.6.8);

i) tests of monitoring and alarm systems (see 12.6.9);

j) test for particulate contamination of pipeline distribution systems (see 12.6.10);

k) tests of the quality of medical air produced by air compressor systems (see 12.6.11);

12.6.8 Tests of all sources of supply

Each source of supply shall be verified against its manufacturer's specifications or tested for all specified operating and emergency conditions according to its manuals and the requirements of this part of ISO 7396.

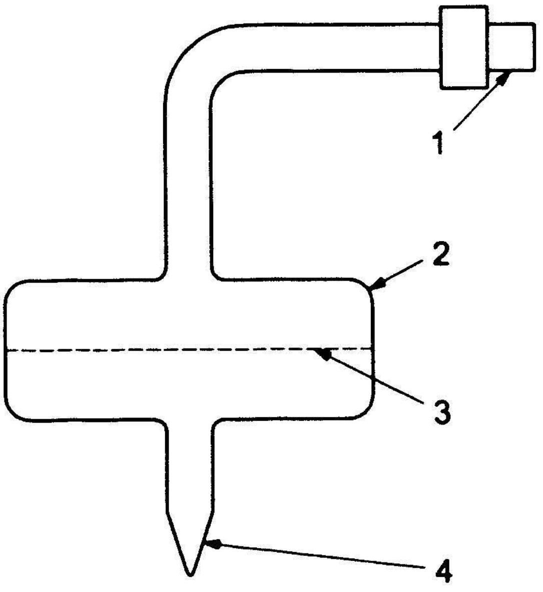
12.6.9 Tests of monitoring and alarm systems

The performance of all monitoring and alarm systems shall be tested in all specified operating and emergency conditions according to their manuals and the requirements of this part of ISO 7396.

12.6.10 Test for particulate contamination of pipeline distribution system

Pipeline distribution systems for compressed medical gases shall be tested for particulate contamination. The test shall be carried out using the device shown in Figure 1 at a flowrate of 150 l/min for at least 15 s.

The filter shall be free from particulate matter when viewed in good light. Purging procedures might be necessary to meet this requirement.



Key

1 gas-specific probe (interchangeable)
2 filter holder specified to withstand 1 000 kPa
3 filter of diameter (50 ± 5) mm and pore size 10 µm
4 calibrated jet (interchangeable) to provide a flowrate of 150 l/min at nominal distribution pressure

Figure 1 — Test device for qualitative determination of particulate contamination of pipeline distribution systems

12.6.11 Tests of the quality of medical air produced by supply systems with air compressor(s)

Medical air supplied by air compressor systems shall be tested for compliance with 5.5.2.1 before filling the pipelines.

12.6.12 Tests of the quality of air for driving surgical tools produced by supply systems with air compressor(s)

Air for driving surgical tools supplied by dedicated air compressor systems shall be tested for compliance with 5.5.2.3 before filling the pipelines.

12.6.13 Tests of the quality of medical air produced by supply systems with proportioning unit(s)

Medical air supplied by proportioning systems shall be tested for compliance with 5.5.3.1 before filling the pipelines.

12.6.14 Tests of the quality of oxygen-enriched air produced by supply systems with oxygen concentrator(s)

Oxygen-enriched air shall be tested for compliance with ISO 10083 before filling the pipelines.

NOTE Regional or national regulations which apply to oxygen-enriched air produced by supply systems with oxygen concentrator(s) can exist.

12.6.15 Filling with specific gas

Each pipeline distribution system for compressed medical gases shall be filled with, and emptied of, its specific gas for a sufficient number of times to displace the test gas. Each terminal unit shall be opened in turn to allow the specific gas to fill the pipeline system.

12.6.16 Tests of gas identity

A gas identity check shall be carried out on each terminal unit after filling with its specific gas, using one or more devices so that positive identification of each medical gas is made.

This test can include a check for absence of odour.

NOTE This test can be carried out at the same time as the tests described in 12.6.11, 12.6.12, 12.6.13 and 12.6.14.

12.7 Certification of the systems

12.7.1 Before a medical gas pipeline system is used, it shall be certified in writing to the healthcare facility that all the requirements of 12.3 and 12.4 have been met. The results of tests showing details of the services and areas tested should be part of the permanent record of the healthcare facility.

Typical forms for this purpose are given in Annex D.

NOTE The certification can be issued in two parts:

— part 1: to cover testing of the requirements of 12.3 and 12.4 [items a) through j)], i.e. up to and including 12.6.10;

— part 2: to cover testing of the requirements of 12.6.11 to 12.6.16 which are carried out after completion of the installation contract but which need not be done immediately.

12.7.2 The system manufacturer shall certify that all drawings and manuals, as required in Clause 13, have been supplied to the owner or client.

12.7.3 When all tests have been completed satisfactorily, all construction labels which have been fixed to terminal units shall be removed.

13 Information to be supplied by the manufacturer

13.1 General

The information to be provided by the manufacturer shall be in accordance with EN 1041 or equivalent national standards.

13.2 Instructions for use

13.2.1 The manufacturer of the complete system or the manufacturers of each component of the medical gas pipeline system (i.e. supply systems, monitoring and alarm system and pipeline distribution system) shall provide the healthcare facility with instructions for use.

NOTE 1 The supply system, monitoring and alarm system and the pipeline distribution system can be supplied by one or several different manufacturers.

NOTE 2 Regional or national regulations which apply to manufacturers of medical devices can exist.

13.2.2 Where national standards concerning information to be provided by the manufacturer do not exist, the instructions for use shall contain the following:

- the name or trade name and address of the manufacturer;
- year of manufacture and, where appropriate, an indication of the date by which the system and its components should be used, in safety, expressed as the year and month;
- any special storage and/or handling conditions;
- any special operating instructions;
- any warning and/or precaution to be taken;
- identification number;
- a technical specification including the performances of the system and how to connect and disconnect detachable parts and accessories;
- a description of all alarm signals and information signals;
- the position in normal condition (i.e. open or closed) of all shut-off valves;
- instructions for recommended periodic checks of function of the system;
- adequate information regarding the medicinal product or products which the system is designed to deliver;
- instructions for the disposal of components or consumables (e.g. oil used in compressors and vacuum pumps, bacterial filters, charcoal filters, desiccants).

13.2.3 The instructions for use given in 13.2.2 shall be drafted taking into account the possibility that several different parties are involved in operation, use and maintenance.

13.3 Operational management information

13.3.1 The manufacturer(s) of each component of the medical gas pipeline system (i.e. supply systems, monitoring and alarm system and pipeline distribution system) shall provide operational management information to the healthcare facility to enable it to draft its Operational Management Document.

13.3.2 The system manufacturer(s) shall provide instructions to the healthcare facility for recommended maintenance tasks and their frequency, and a list of recommended spare parts, if applicable.

13.3.3 The manufacturer of the complete system shall provide information to enable the healthcare facility to prepare a specific emergency procedure to respond to catastrophic failure of one or more pipeline system(s), where the medical gas supplies to all medical devices might cease simultaneously.

NOTE Informative guidelines for the preparation of the Operational Management Document are given in Annex G. Informative guidelines for risk management are given in Annex F.

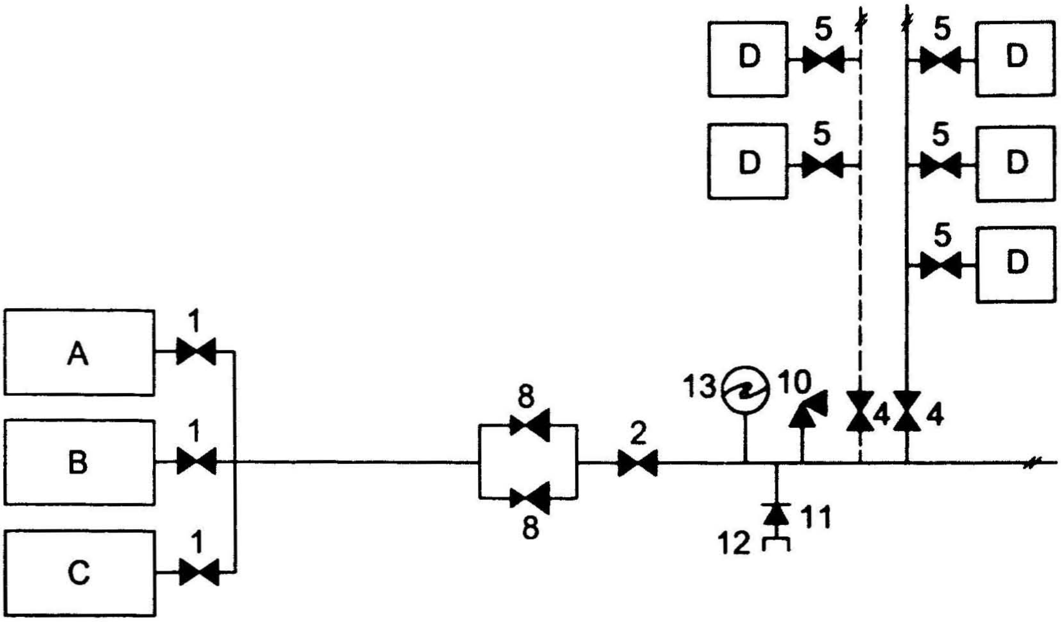
13.4 "As-installed" drawings

13.4.1 A separate set of "as-installed" mechanical drawings which show the actual locations of the pipelines, the diameters of the pipelines, shut-off valves (including their identification, as appropriate) and all other components shall be maintained during construction, and shall be brought up to date as changes are made. These drawings shall include details which will enable buried or concealed pipelines to be located.

13.4.2 A complete set of "as-installed" drawings of the pipeline system as specified in 13.4.1 shall be presented to the healthcare facility for inclusion as part of the permanent record of the pipeline system.

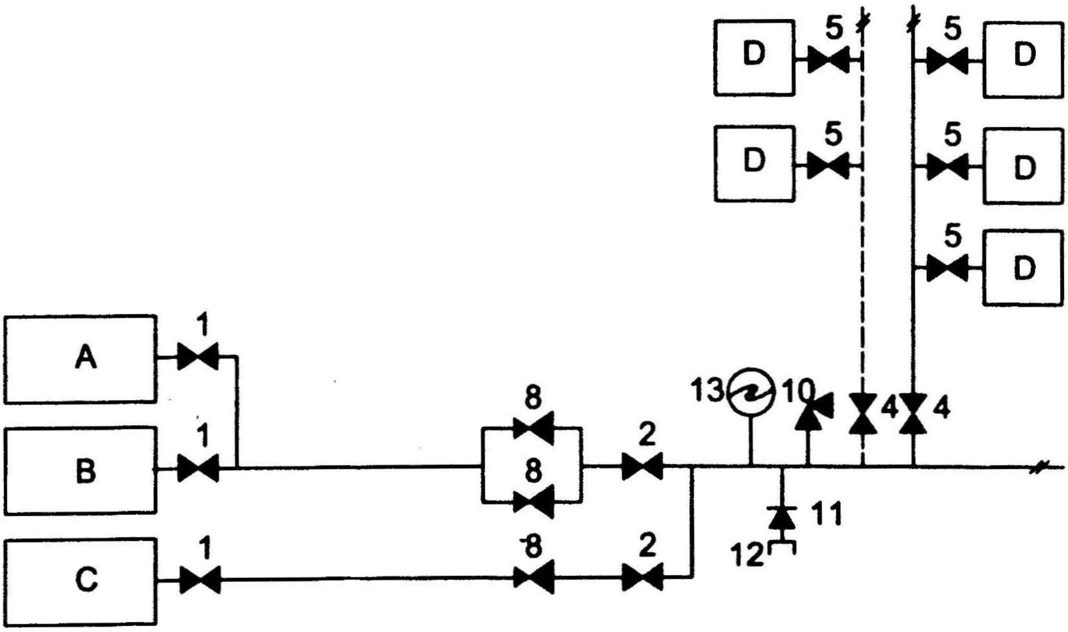
13.5 Electrical diagrams

Electrical diagrams for the components supplied shall be provided by the system manufacturer to the healthcare facility.



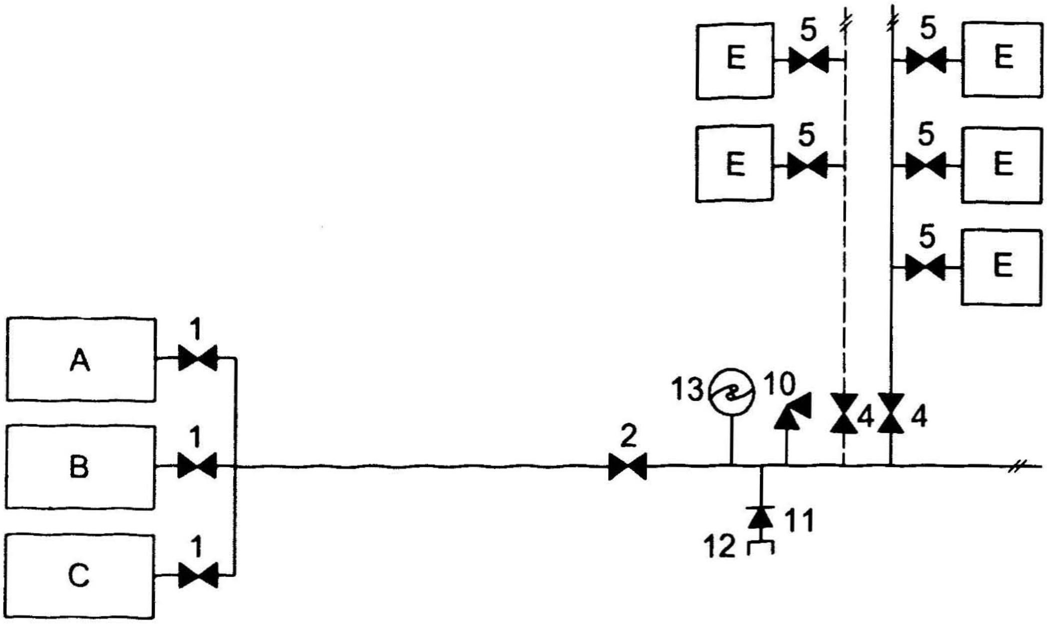
NOTE See Tables A.2 and A.3 for keys to components and subassemblies.

Figure A.1 — Single-stage pipeline system (three sources of supply)



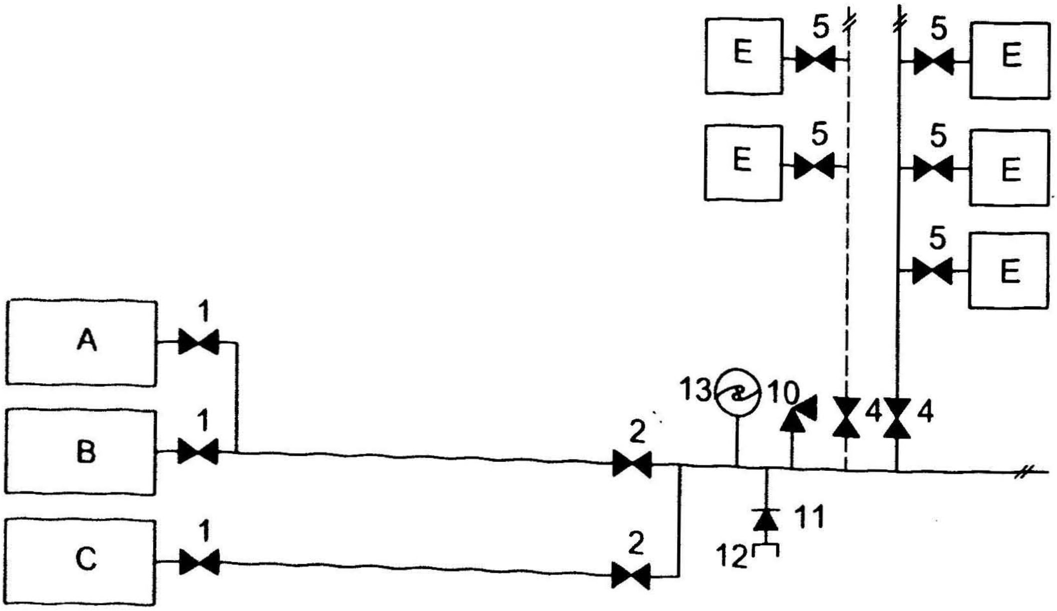
NOTE See Tables A.2 and A.3 for keys to components and subassemblies.

Figure A.2 — Single-stage pipeline system (three sources of supply) — Alternative arrangement of reserve supply connection



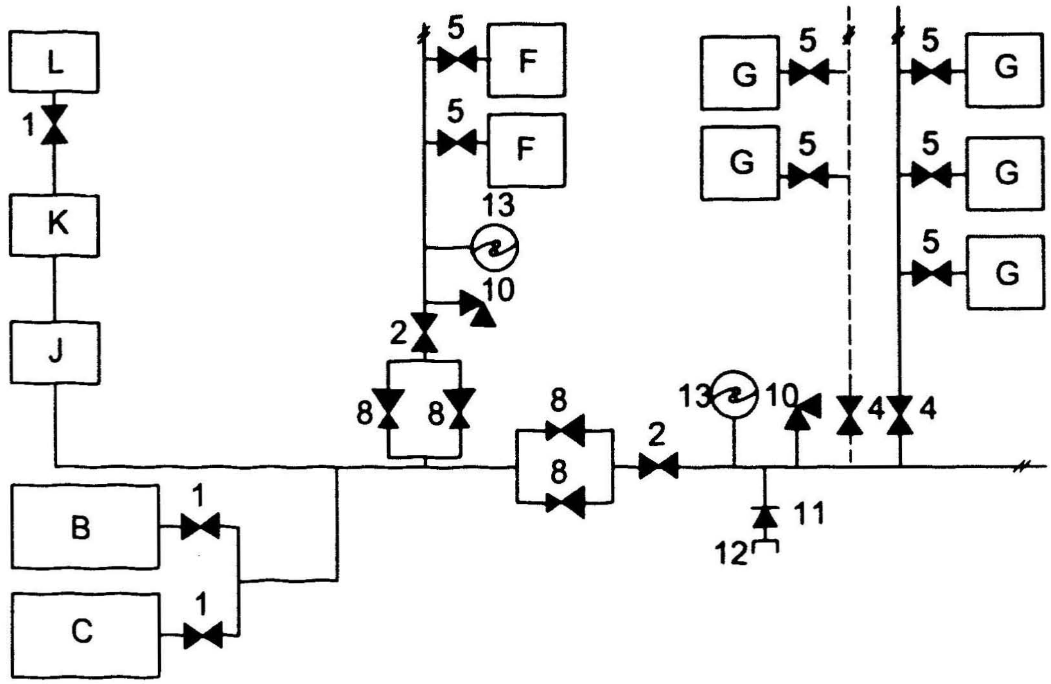
NOTE See Tables A 2 and A 3 for keys to components and subassemblies.

Figure A.3 — Double-stage pipeline system (three sources of supply)



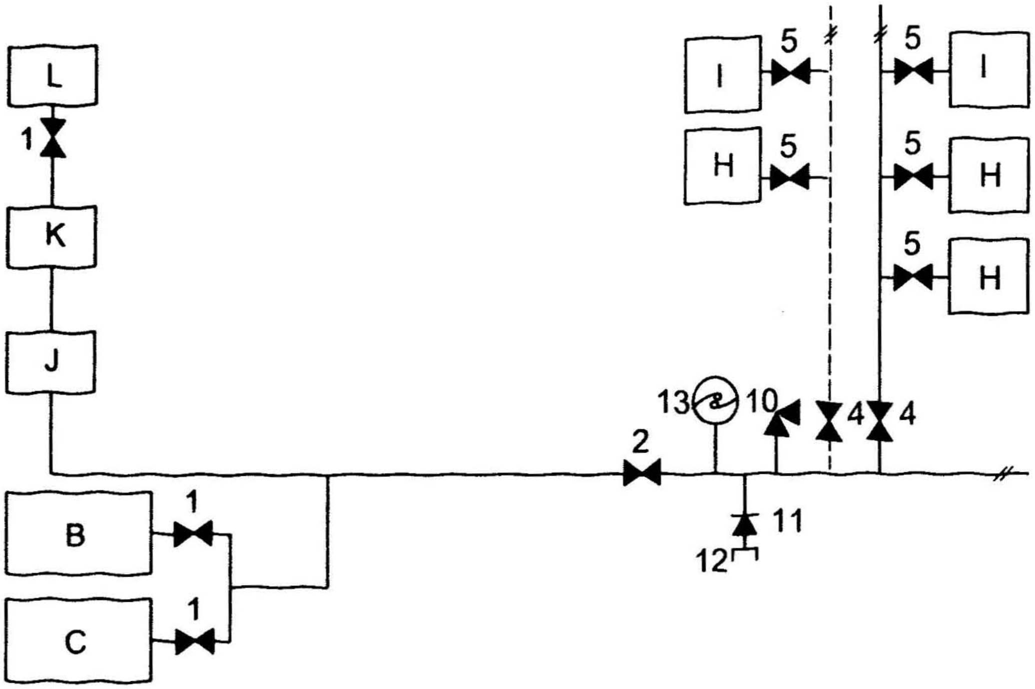
NOTE See Tables A 2 and A 3 for keys to components and subassemblies.

Figure A.4 — Double-stage pipeline system (three sources of supply) — Alternative arrangement of reserve supply connection



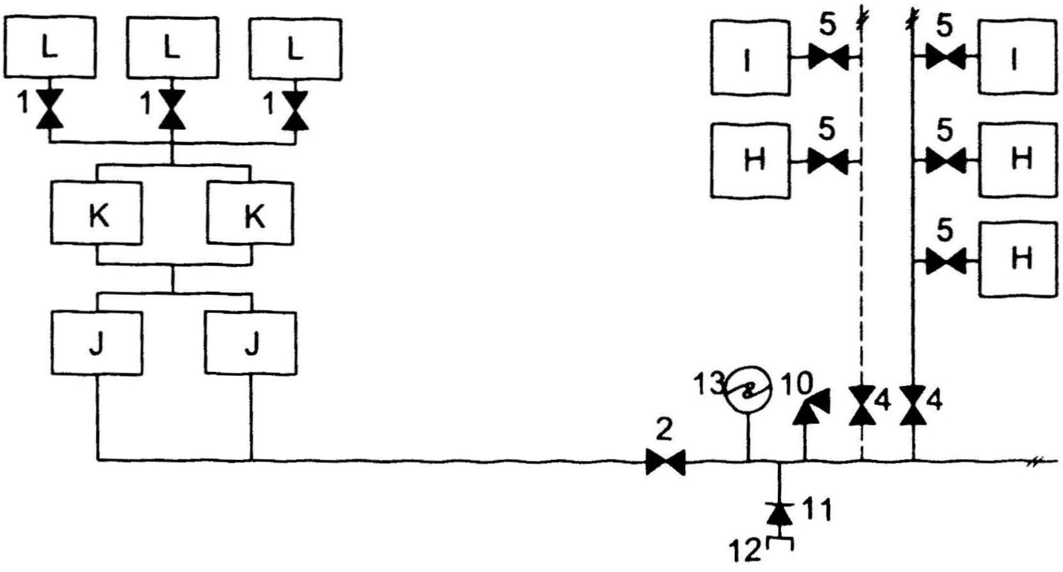
NOTE See Tables A.2 and A.3 for keys to components and subassemblies.

Figure A.5 — Single-stage pipeline system with air compressor supply system (one air compressor source – two cylinder sources)



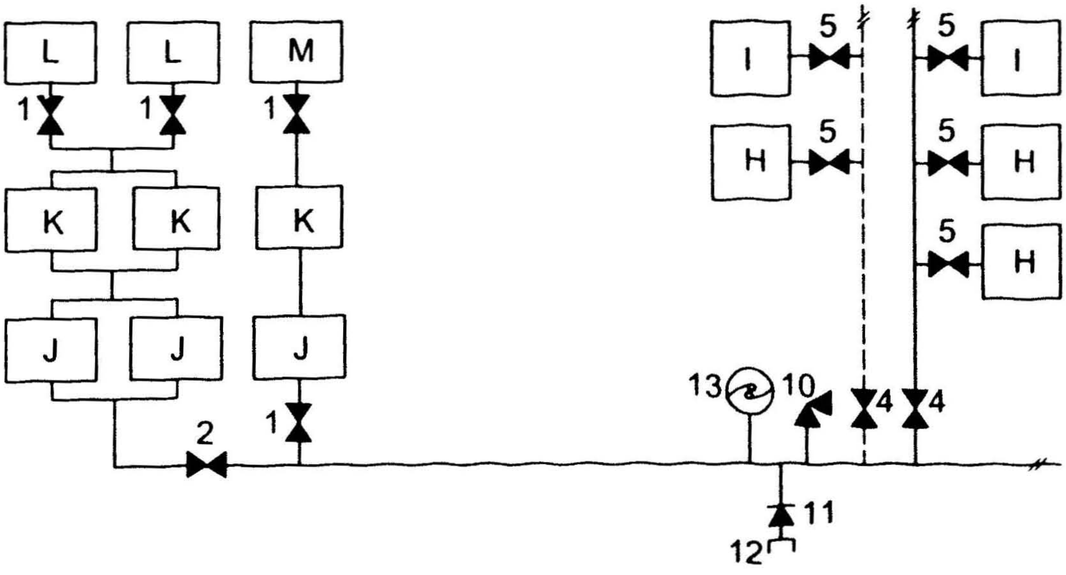
NOTE See Tables A.2 and A.3 for keys to components and subassemblies.

Figure A.6 — Double-stage pipeline system with air compressor supply system (one air compressor source – two cylinder sources)



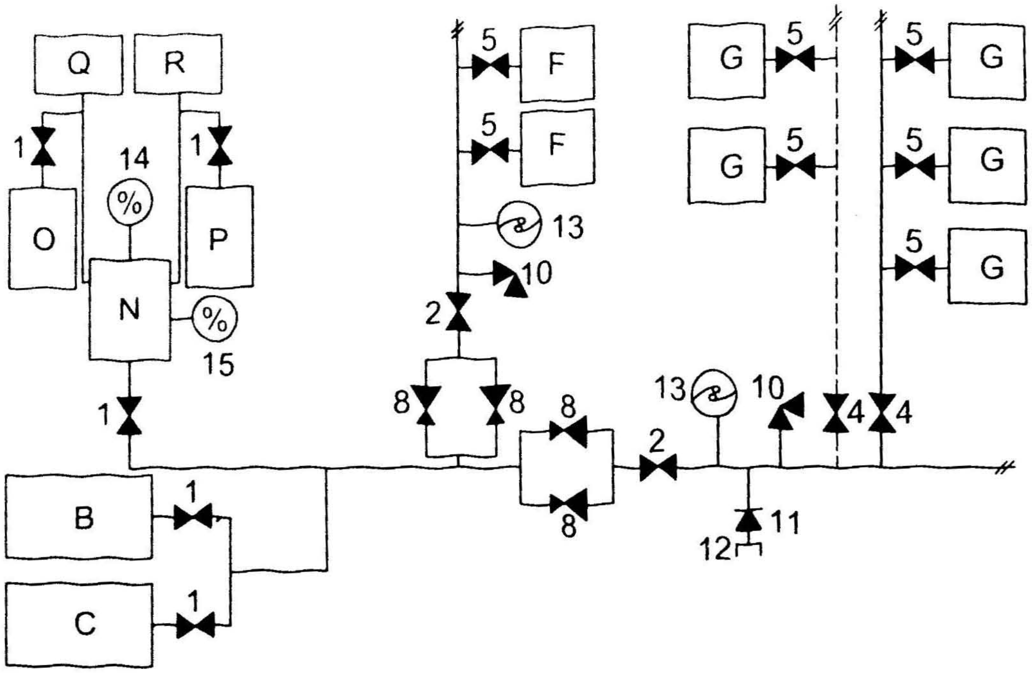
NOTE See Tables A.2 and A.3 for keys to components and subassemblies

Figure A.14 — Double-stage pipeline system with air compressor supply system (three air compressor sources)



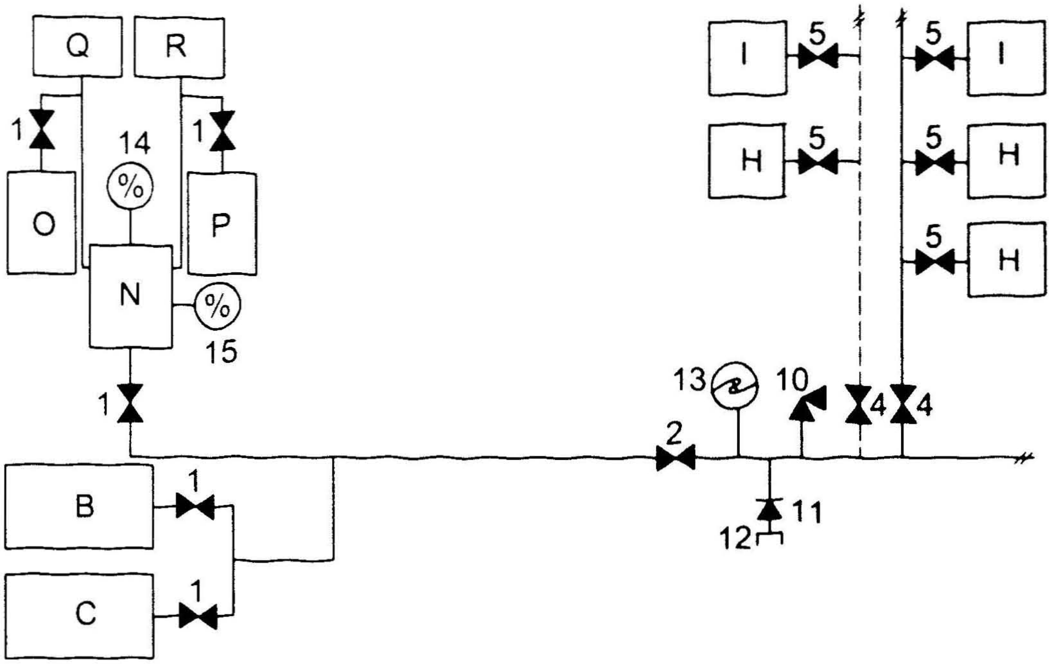
NOTE See Tables A.2 and A 3 for keys to components and subassemblies

Figure A.15 — Double-stage pipeline system with air compressor supply system (three air compressor sources) — Alternative arrangement of reserve air compressor supply connection



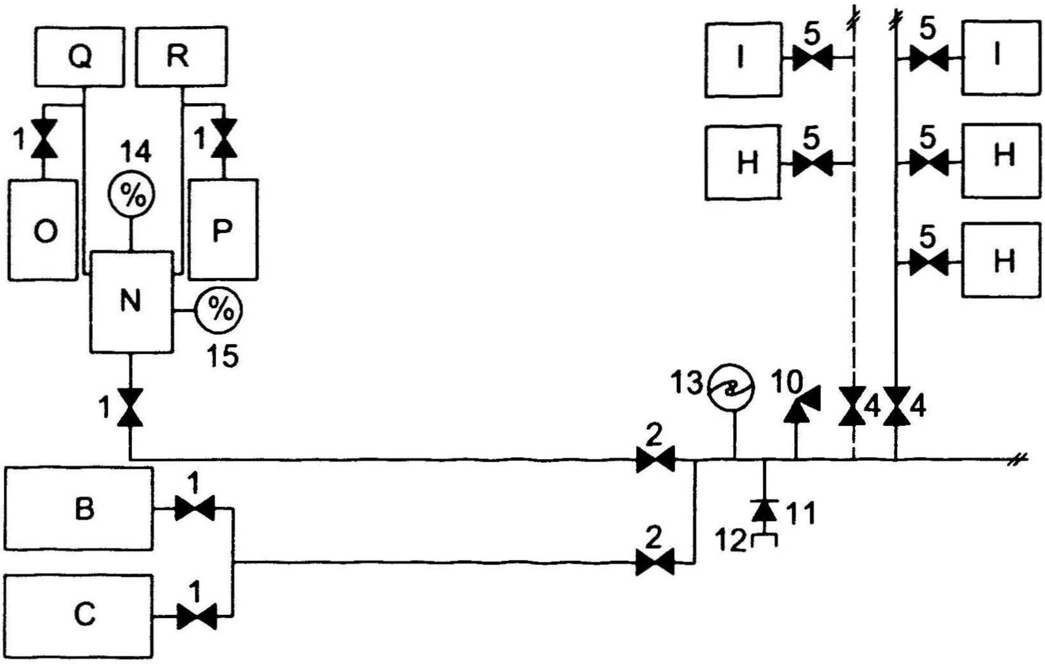
NOTE See Tables A 2 and A 3 for keys to components and subassemblies.

Figure A.16 — Single-stage pipeline system with proportioning supply system (one proportioning unit – two cylinder sources)



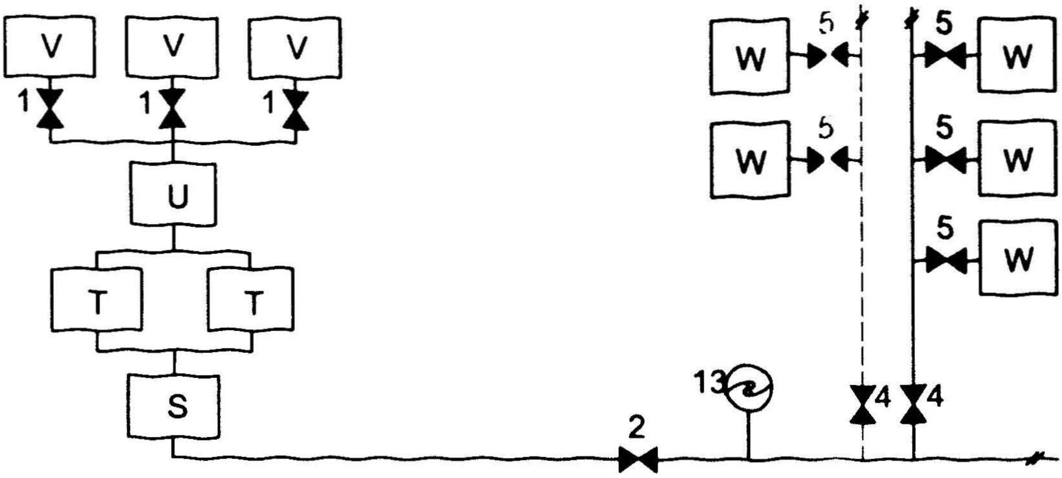
NOTE See Tables A 2 and A 3 for keys to components and subassemblies

Figure A.17 — Double-stage pipeline system with proportioning supply system (one proportioning unit – two cylinder sources)



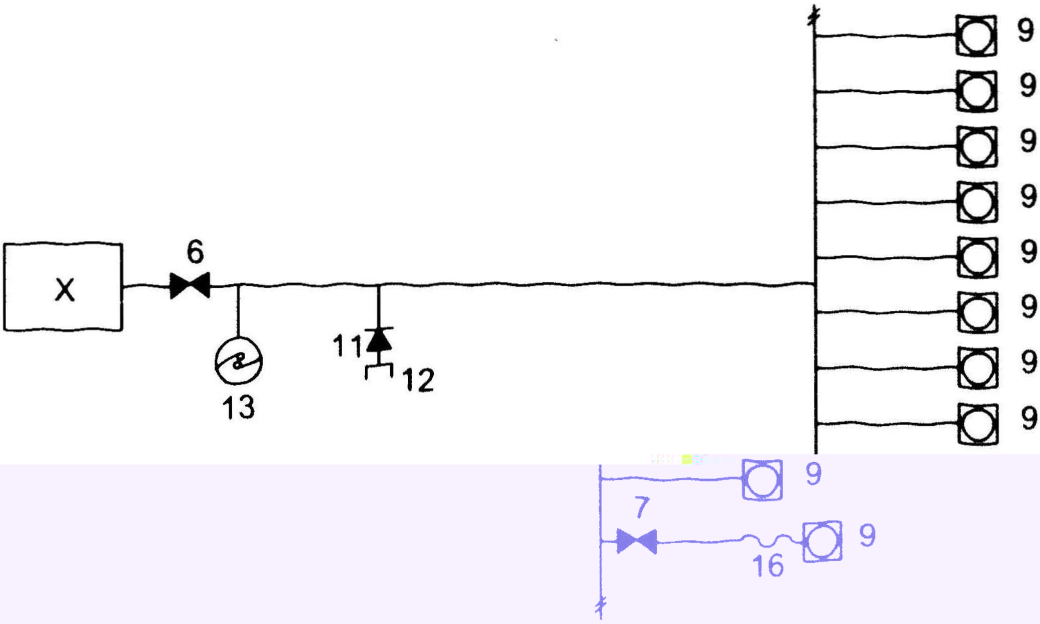
NOTE See Tables A.2 and A.3 for keys to components and subassemblies.

Figure A.18 — Double-stage pipeline system with proportioning supply system (one proportioning unit – two cylinder sources) — Alternative arrangement of secondary and reserve supply connection



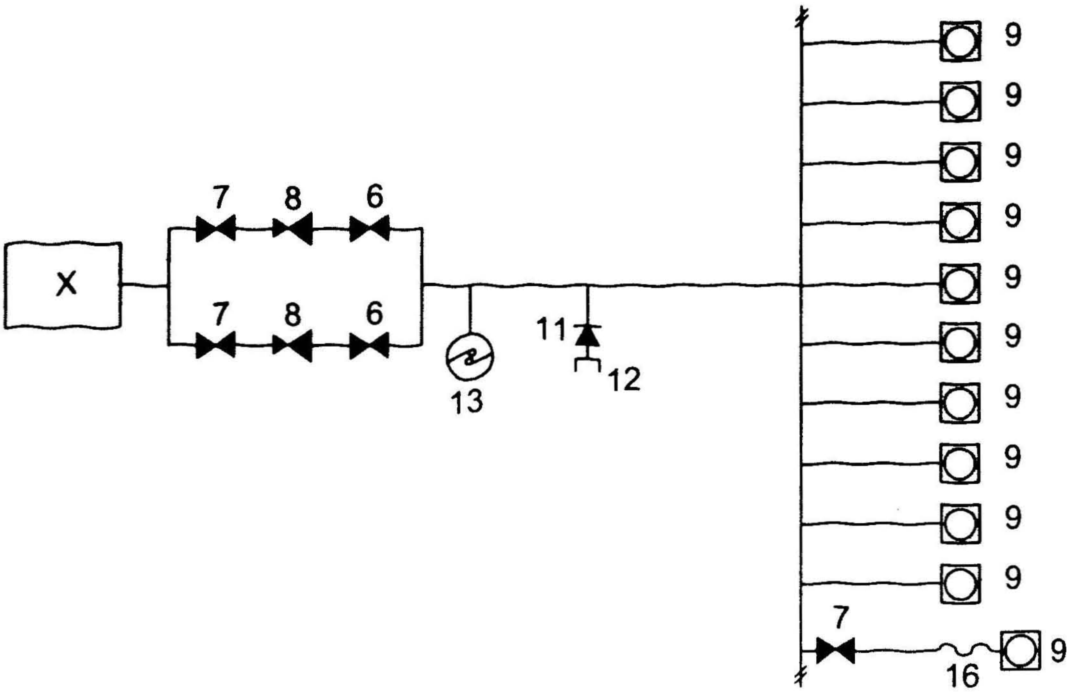
NOTE See Tables A.2 and A.3 for keys to components and subassemblies.

Figure A.27 — Vacuum pipeline system (three vacuum sources)



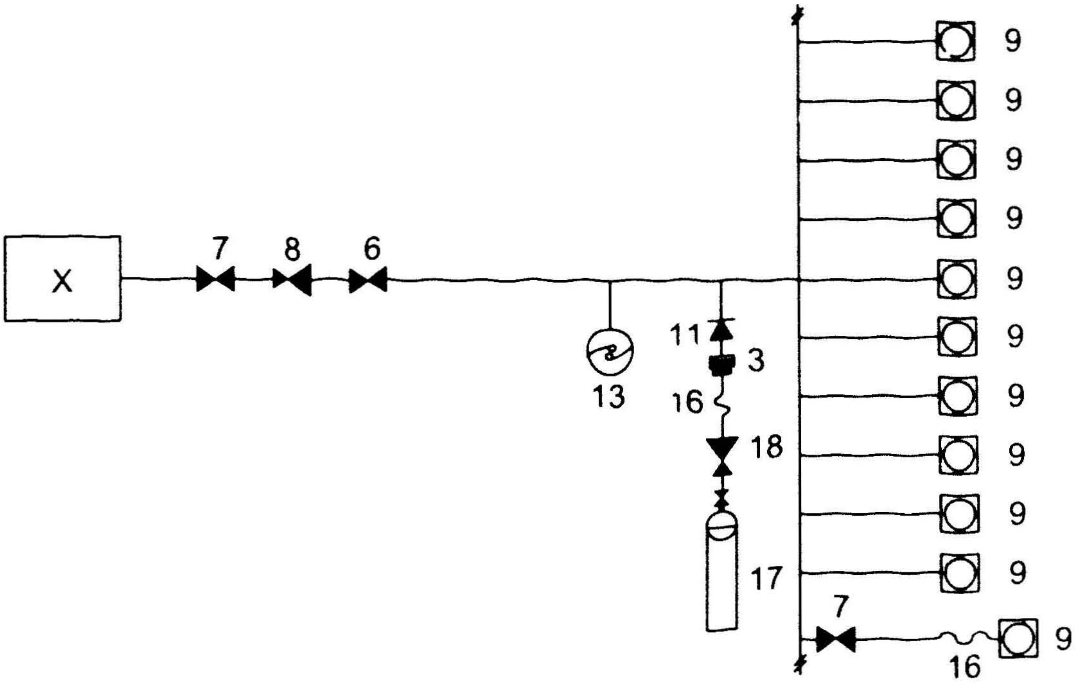
e Tables A 2 and A 3 for keys to components and subassemblies NOTE Se

ure A.28 — Area distribution system for single-stage pipeline distribution system (with no additional pressure regulators) Fig



NOTE See Tables A 2 and A 3 for keys to components and subassemblies.

Figure A.29 — Area distribution system for double-stage pipeline distribution system with two parallel line pressure regulators



NOTE See Tables A.2 and A.3 for keys to components and subassemblies

Figure A.30 — Area distribution system for double-stage pipeline distribution system — Additional cylinder with pressure regulator permanently connected to pipeline

Annex B
(informative)

Guidelines for location of cylinder manifolds, cylinder storage areas and stationary vessels for cryogenic or non-cryogenic liquids

B.1 Location of cylinder manifolds

A supply system with cylinders should be installed in a well-ventilated and fire-resistant room that is specially constructed or suitably modified. Alternatively, it can be installed in the open air under cover, protected from the weather, and the area fenced to prevent access by unauthorized persons.

NOTE Regional or national regulations which apply to the location of cylinder manifolds can exist

C.3.2.2.2 Depressurize the pipeline system downstream of each area shut-off valve to 100 kPa by opening a terminal unit. Close the terminal unit.

C.3.2.2.3 Check that the pressure increase does not exceed 5 kPa after 15 min.

C.3.2.2.4 Note the total number and the location of terminal units controlled by each area shut-off valve and check that these terminal units are correctly labelled.

C.3.2.3 Test results

Record the results on Form D.7.

C.3.3 Test for cross-connection (see 12.6.3)

C.3.3.1 General

In no circumstances should this test be carried out by pressurizing more than one pipeline system at a time. All pipeline systems should be at atmospheric pressure and all shut-off valves open. A single test gas source should be used and connected to only one pipeline system at a time. That pipeline system should be kept at nominal distribution pressure throughout the test. In the case of the vacuum pipeline system, the vacuum supply system should be used. This test should be applied to all terminal units.

C.3.3.2 Example of procedure

C.3.3.2.1 Pressurize (or evacuate) the pipeline system to be tested to nominal distribution pressure.

C.3.3.2.2 Check that gas flows through every terminal unit of the pipeline system under test.

C.3.3.2.3 Check that there is no gas flow from any terminal unit of any other pipeline system when opened with a gas-specific probe and that there are, therefore, no cross-connections.

C.3.3.2.4 With all the other pipeline systems at atmospheric pressure, repeat the procedure in C.3.3.2.1 through C.3.3.2.3 on each pipeline system in turn, including vacuum, preferably at one session.

C.3.3.2.5 Repeat the test in full if any modifications are made to the pipeline systems during the commissioning procedure.

C.3.3.3 Test results

Record the results on Form D.8.

C.3.4 Test for obstruction and flow (see 12.6.4)

C.3.4.1 General

These tests can be carried out at the same time as the cross-connection test described in C.3.3. In this case, only one pipeline system at a time is under pressure. Alternatively, after completion of the tests given in C.3.3, all pipeline systems can be pressurized at nominal distribution pressure and the tests described in C.3.5 and C.3.6 carried out simultaneously.

C.3.4.2 Example of procedure

Insert a gas-specific test probe with pressure gauge and flow-measuring device into each terminal unit in turn. Check that the pressure change between zero flow and the specified test flow at each terminal unit does not exceed the value given in Table 4.

C.3.4.3 Test results

Record the results on Forms D.9 and D.10.

C.3.5 Check of terminal units and NIST or DISS connectors for mechanical function, gas specificity and identification (see 12.6.5)

C.3.5.1 General

All terminal units should be complete with fascia plate.

These tests can be carried out at the same time as the cross-connection test described in C.3.3. In this case, only one pipeline system at a time is under pressure. Alternatively, after completion of the tests given in C.3.3 all pipeline systems can be pressurized at nominal distribution pressure and the tests described in C.3.5 and C.3.6 carried out simultaneously.

C.3.5.2 Example of procedure

C.3.5.2.1 Check that the gas-specific probe can be easily inserted, captured and released. If an anti-swivel device is provided, check that this retains the probe in the correct orientation.

C.3.5.2.2 Check that no gas is released at any terminal unit by insertion of the probes of any other gases and that no probes for other gases can be captured.

C.3.5 2.3 Check that all NIST or DISS connectors accept the appropriate nipples and that a mechanical connection is made. Check that the NIST or DISS nipples for all other gases do not fit the connectors under test.

C.3.5.2.4 Check that all terminal units are identified and labelled correctly and meet the requirements specified in 12.6.5.

C.3.5.3 Test results

Record the results on Forms D.9 and D.10.

C.3.6 Tests of system performance (see 12.6.6)

C.3.6.1 General

These tests should be carried out on one system at a time. All shut-off valves should be open. Connect a supply of test gas of sufficient capacity to deliver the system design flow for several minutes at the inlet to the pipeline distribution system. The vacuum supply system should be used to test the vacuum pipeline system.

C.3.6.2 Example of procedure

C.3.6.2.1 Pressurize or evacuate the pipeline to a pressure not greater than the maximum distribution pressure or vacuum. Record the pressure.

C.3.6.2.2 Insert probes into selected terminal units throughout the pipeline under test to provide a total flow equal to the system design flow. Each probe shall be equipped with a calibrated orifice.

C.3.6.2.3 Observe and record the gauge pressure at the specified flow at selected terminal units throughout the pipeline system. The selected terminal units should be remote from the supply system (e.g. at the end of each branch).

C.3.6.2.4 Check that the pressure at each of the selected terminal units is within the limits given in 7.2.2, 7.2.3 and 7.2.4.

C.3.6.2.5 Depressurize the system and repeat the test for each service.

C.3.6.3 Test results

Record the results on Form D.11.

C.3.7 Checks of system performance by verification of calculation (see 12.6.6)

C.3.7.1 General

A check of system performance by verification of calculations is considered an alternative means to show compliance to the requirements given in Table 2, 7.2.2, 7.2.3 and 7.2.4.

C.3.7.2 Check results

Record the check results on Form D.11.

C.3.8 Test of pressure-relief valves (see 12.6.7)

C.3.8.1 General

If type-tested and certified pressure-relief valves are installed, tests of relief valve function are not required, provided that the requirements of 7.2.5 and 7.2.6 are met.

If the pressure-relief valves fitted are not type-tested and certified, their performance should be verified according to the procedure given in C.3.8.2.

C.3.8.2 Example of procedure

C.3.8.2.1 Inspect each pressure-relief valve to check the discharge capacity and the set pressure.

C.3.8.2.2 Inspect the certification supplied with each pressure-relief valve.

C.3.8.2.3 Inspect the installation of the pressure-relief valves to verify that they are correctly vented.

C.3.8.2.4 Isolate a section of pipeline in which the pressure-relief valve to be tested is located.

C.3.8.2.5 Gradually increase the pressure in this section of the pipeline and note the pressure at which the pressure-relief valve opens and the pressure at which it allows maximum discharge.

C.3.8.2.6 Gradually reduce the pressure to that normally present in the section under test and note the value at which the pressure-relief valve reseats and is gas-tight.

C.3.8.2.7 Verify that the pressure at which the pressure-relief valve operates permits the system to meet the requirements of 7.2.5 or 7.2.6 as appropriate.

C.3.8.3 Test results

Record the results on Form D.12.

C.3.9 Tests on sources of supply (see 12.6.8)

C.3.9.1 General

All sources of supply should be installed and connected to normal and emergency electrical power supplies, as required. Specific checklists for each supply system should have been prepared to meet the requirements of Clause 5 and the manufacturer's specifications.

C.3.9.2 Example of procedure

Test all components for leakage. Test air compressor systems for leaks during normal operation. Minor leaks detectable as bubbles are acceptable. Check the function and operating parameters of each supply system from the checklist. Check that the supply system operates on the emergency power supply. Verify that the test results conform to the manufacturer's specifications and the requirements of Clause 5. Verify that the system design flow requirements are met.

C.3.9.3 Test results

Record the results on Form D.13.

C.3.10 Tests of monitoring and alarm systems (see 12.6.9)

C.3.10.1 General

These tests should be carried out for one function at a time, on one system at a time. All alarm systems should be fully installed and in operation.

C.3.10.2 Example of procedure

C.3.10.2.1 Check that all alarms are activated with an appropriate change in the local system condition (for example pressure, moisture content, liquid level and system change-over). Record the settings at which alarm sensors switch on and off.

C.3.10.2.2 Observe all alarm functions, including visual and auditory signals, resetting of the auditory signals and lamp test. Check that the visual and auditory characteristics of all signals are in accordance with Clause 6, if applicable.

C.3.10.2.3 Verify that all monitors and alarms operate with the appropriate changes in pipeline system conditions and operate from the normal and emergency electrical power supplies.

C.3.10.2.4 Verify that all monitors and alarms comply with the requirements of Clause 6.

C.3.10.3 Test results

Record the results on Form D.14.1 and Form D.14.2.

C.3.11 Test for particulate contamination (see 12.6.10)

C.3.11.1 General

The compressed medical gas pipeline systems should be at nominal distribution pressure and filled with test gas.

Annex D
(informative)

Typical forms for certification of the medical gas pipeline system

The forms given in this annex are to be completed during testing and commissioning of pipeline systems for compressed medical gases and vacuum in accordance with Annex C.

Form D.1.1 — Summary of tests of requirements of 12.3 and 12.4 [items a) through j)], i.e. up to and including 12.6.10 (see 12.7.1)

Healthcare facility____________________________ Area identification ________________________

This is to certify that the following tests and procedures have been carried out satisfactorily on the medical gases and vacuum pipeline systems at ____________________________ healthcare facility.

(Sheet .... of .... sheets)

Form	Description of tests and procedures	Test required Yes/No	Procedure	Specification	Date of completion of tests and procedures
D.2	Marking and supports		C.2.1	12.5.1	
D.3	Design specification		C.2.2	12.5.2	
D.4.1	Mechanical integrity of vacuum pipeline systems		C.3.1.1	12.6.1.1	
D.4.2	Leakage into vacuum pipeline systems		C.3.1.2	12.6.1.2	
D.5.1	Mechanical integrity of compressed medical gas pipeline systems		C.3.1.3	12.6.1.3	
D.5.2	Leakage from compressed medical gas pipeline systems (upstream sections)		C.3.1.4 or C.3.1.6	12.6.1.4 or 12.6.1.6	
D.5.3	Leakage from compressed medical gas pipeline systems (downstream sections)		C.3.1.4 or C.3.1.6	12.6.1.4 or 12.6.1.6	
D.6.1	Combined leakage and mechanical integrity of compressed medical gas pipeline systems (before concealment)		C.3.1.5	12.6.1.5	
D.6.2	Combined leakage and mechanical integrity of compressed medical gas pipeline systems (after concealment)		C.3.1.6	12.6.1.6	
D.7	Area shut-off valve leakage, closure, zoning and identification		C.3.2	12.6.2	
D.8	Cross-connection		C.3.3	12.6.3	
D.9	Terminal units: obstruction and flow, mechanical function, identification, gas specificity		C.3.4 C.3.5	12.6.4 12.6.5	
D.10	NIST or DISS connectors: obstruction and flow, mechanical function, identification, gas specificity		C.3.4 C.3.5	12.6.4 12.6.5	
D.11	System performance		C.3.6 C.3.7	12.6.6	
D.12	Pressure-relief valves		C.3.8	12.6.7	
D.13	Sources of supply		C.3.9	12.6.8	
D.14.1	Emergency clinical and operating alarms		C.3.10	12.6.9	
D.14.2	Operating alarms		C.3.10	12.6.9	
D.15	Particulate contamination		C.3.11	12.6.10	

Manufacturer's Representative

Position____________________________ Signature________________________

Date ____________________________ Name ________________________

Authorized Person

Position____________________________ Signature________________________

Date ____________________________ Name ________________________

Form D.1.2 — Summary of tests of requirements of 12.6.11 to 12.6.16 (see 12.7.1)

Healthcare facility____________________________ Area identification ________________________

This is to certify that the following tests and procedures have been carried out satisfactorily on the medical gases and vacuum pipeline systems at ______________________________ healthcare facility.

(Sheet ……… of ……… sheets)

Form	Description of tests and procedures	Test required Yes/No	Procedure	Specification	Date of completion of tests and procedures
D.16	Quality of medical air produced by supply systems with air compressor(s)		C.3.12	12.6.11	
D.17	Quality of air for driving surgical tools produced by supply systems with air compressor(s)		C.3.12	12.6.12	
D.18	Quality of medical air produced by supply systems with proportioning unit(s)		C.3.13	12.6.13	
D.19	Quality of oxygen-enriched air produced by supply systems with oxygen concentrator(s)		C.3.14	12.6.14	
D.20	Filling with specific gas		C.3.15	12.6.15	
D.21.1	Gas identity with oxygen analyser		C.3.16	12.6.16	
D.21.2	Gas identity with different pressures		C.3.16	12.6.16	
D.21.3	Gas identity with gas-specific analyser		C.3.16	12.6.16	
	Construction labels removed				

Manufacturer's Representative

Position __________________________ Signature ________________________

Date ____________________________ Name __________________________

Authorized Person

Position __________________________ Signature ________________________

Date ____________________________ Name __________________________

Form D.2 — Inspection of pipeline markings and supports

Healthcare facility ________________________ Area identification ________________________

(Sheet .... of .... sheets)

This is to certify that pipeline marking and supports have been inspected before concealment.

Medical gas	**Section inspected**	**Markings** Pass/Fail	**Supports** Pass/Fail

Manufacturer's Representative

Position ________________________ Signature ________________________

Date ________________________ Name ________________________

Authorized Person

Position ________________________ Signature ________________________

Date ________________________ Name ________________________

Form D.5.2 — Tests for leakage from compressed medical gas pipeline systems — Test for leakage on portion(s) upstream of area shut-off valves (or line pressure regulators)

Healthcare facility________________________________ Area identification ______________________________

(Sheet .... of .... sheets)

This is to certify that a leakage test was carried out on the pipeline system(s) During the test, the pressures shown below were measured.

Medical gas	**Portion upstream of area shut-off valve**	**Test pressure** kPa	**Test period** h	**Pressure drop** Δp kPa	**Initial temp.** °C	**Final temp.** °C	**Pressure change due to temp.** kPa	**Pass/Fail** $\Delta p \leq 0{,}025$ %/h

Measuring instrument(s) used ____

Manufacturer's Representative

Position ________________________________ Signature ______________________________

Date ___________________________________ Name _________________________________

Authorized Person

Position ________________________________ Signature ______________________________

Date ___________________________________ Name _________________________________

Form D.5.3 — Tests for leakage from compressed medical gas pipeline systems — Test for leakage on portion(s) downstream of area shut-off valves (or line pressure regulators)

Healthcare facility____________________________ Area identification ________________________

COMPLETE INSTALLATION *(Sheet .... of .... sheets)*

This is to certify that a leakage test was carried out on the piped system. During the test, the pressures shown below were observed.

Medical gas	**Portion downstream of area shut-off valve**	**Test pressure** kPa	**Test period** h	**Pressure drop** Δp kPa	**Initial temp.** °C	**Final temp.** °C	**Pressure change due to temp.** kPa	**Pass/Fail** $\Delta p \leqslant 0{,}4$ %/h or $\leqslant 0{,}6$ %/h [a]

[a] Check that in each section downstream of each area shut-off valve (or line pressure regulator), the pressure drop does not exceed 0,4 %/h of the initial test pressure in sections not including flexible hoses in medical supply units or 0,6 %/hr of the initial test pressure in sections including flexible hoses in medical supply units.

Measuring instrument(s) used ____________________________________

Manufacturer's Representative

Position____________________________ Signature________________________

Date ____________________________ Name ________________________

Authorized Person

Position____________________________ Signature________________________

Date ____________________________ Name ________________________

Form D.6.1 — Combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems

This is to certify that a mechanical integrity test was carried out before concealment on the medical gas pipeline system(s).

Medical gas	**Section tested**	**Test pressure** kPa	**Test period** min	**Pass/Fail**

This is to certify that a leakage test was carried out before concealment on the medical gas pipeline system(s).

During the test, the pressures shown below were measured.

Medical gas	**Section tested**	**Test pressure** kPa	**Test period** h	**Pressure drop** Δp kPa	**Initial temp.** °C	**Final temp.** °C	**Pressure change due to temp.** kPa	**Pass/Fail** $\Delta p \leqslant 0{,}025$ %/h

Measuring instrument(s) used ______________________________

Manufacturer's Representative

Position ______________________ Signature ______________________

Date ______________________ Name ______________________

Authorized Person

Position ______________________ Signature ______________________

Date ______________________ Name ______________________

Form D.6.2 — Combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems

Healthcare facility____________________ Area identification ____________________

COMPLETE INSTALLATION *(Sheet .... of .... sheets)*

This is to certify that a mechanical integrity test was carried out after concealment on the medical gas pipeline system(s).

Medical gas	**Section tested**	**Test pressure** kPa	**Test period** min	**Pass/Fail**

For the tests for leakage, use Form D.5.2 and Form D.5.3.

Measuring instrument(s) used ____________________

Manufacturer's Representative

Position____________________ Signature____________________

Date ____________________ Name ____________________

Authorized Person

Position____________________ Signature____________________

Date ____________________ Name ____________________

Form D.11 — Tests or checks of system performance

Healthcare facility____________________ Area identification ____________________

COMPLETE INSTALLATION *(Sheet ……… of ……… sheets)*

This is to certify that the__________ pipeline was tested as follows:

System design flowrate __________ l/min

Terminal unit test flowrate __________ l/min

Nominal distribution pressure __________ kPa

Minimum distribution pressure allowed __________ kPa

Maximum distribution pressure allowed__________ kPa

Room identification	Terminal unit identification	Specifications met Pass/Fail

Measuring instrument(s) used ____

Manufacturer's Representative

Position ____________________ Signature ____________________

Date ____________________ Name ____________________

Authorized Person

Position ____________________ Signature ____________________

Date ____________________ Name ____________________

Form D.12 — Tests of pressure-relief valves

Healthcare facility ______________________ Area identification ______________________

COMPLETE INSTALLATION *(Sheet .... of .... sheets)*

This is to certify that the pressure-relief valves fitted to the pipeline system have been inspected/tested (delete as appropriate) as follows:

Medical gas	**Pressure-relief valve identification**	**Location**	**Full discharge capacity** l/min	**Full discharge pressure** kPa	**Correct venting** Yes/No	**Reseating pressure** kPa

Measuring instrument(s) used ______________________

Manufacturer's Representative

Position ______________________ Signature ______________________

Date ______________________ **Name** ______________________

Authorized Person

Position ______________________ Signature ______________________

Date ______________________ **Name** ______________________

Form D.13 — Tests of all sources of supply

Healthcare facility____________________ Area identification ____________________

COMPLETE INSTALLATION *(Sheet .... of .... sheets)*

This is to certify that the following sources of supply have been inspected/tested.

Source of supply	**Operating condition specification**	**Pass/Fail**	**Emergency condition specification**	**Pass/Fail**
Manifold				
Manifold				
Manifold				
Manifold				
Manifold				
Cryogenic oxygen system				
Air compressor system				
Proportioning system				
Oxygen concentrator system				
Vacuum system				

Manufacturer's Representative

Position ____________________ Signature ____________________

Date ____________________ Name ____________________

Authorized Person

Position ____________________ Signature ____________________

Date ____________________ Name ____________________

Form D.14.1 — Tests of emergency clinical and operating alarms

Healthcare facility ____________________ Area identification ____________________

COMPLETE INSTALLATION *(Sheet .... of .... sheets)*

This is to certify that the monitoring and alarm systems have been tested and comply with the specifications.

Function tested	**Oxygen**	**Nitrous oxide**	**Vacuum**	**Medical air**	**Air for driving surgical tools**	**Carbon dioxide**	**Oxygen-enriched air**	**Nitrogen for driving surgical tools**	**Oxygen/ nitrous oxide mixture**
Specified alarm maximum pressure									
Observed alarm maximum pressure									
Return to normal from maximum pressure									
Specified alarm minimum pressure									
Observed alarm minimum pressure									
Return to normal from minimum pressure									
Marking									
Visual characteristics									
Auditory characteristics									
All visual and audible signal functions									
Connection to emergency power supply									

Measuring instrument(s) used ____________________

Manufacturer's Representative

Position ____________________ Signature ____________________

Date ____________________ Name ____________________

Authorized Person

Position ____________________ Signature ____________________

Date ____________________ Name ____________________

Form D.18 — Tests of the quality of medical air produced by supply systems with proportioning unit(s)

Healthcare facility________________________ Area identification ________________________

COMPLETE INSTALLATION *(Sheet .... of .... sheets)*

This is to certify that the medical air produced by the supply system with proportioning unit(s) has been tested before filling the pipeline and complies with the requirements of 5.5.3.1 as follows:

Oxygen concentration $\geqslant$ 19,95 % $\leqslant$ 23,63 %	**Water vapour content** $\leqslant$ 67 ml/m^3

Measuring instrument(s) used ____

Manufacturer's Representative

Position ________________________ Signature ________________________

Date ________________________ Name ________________________

Authorized Person

Position ________________________ Signature ________________________

Date ________________________ Name ________________________

Form D 19 — Tests of the quality of oxygen-enriched air produced by supply systems with oxygen concentrator(s)

Healthcare facility ______________________ Area identification ______________________

COMPLETE INSTALLATION (Sheet of sheets)

This is to certify that the quality of oxygen-enriched air supplied by the supply system with oxygen concentrator(s) has been tested according to ISO 10083 before filling the pipelines

Oxygen concentration	Carbon monoxide	Carbon dioxide	Particulate contamination	Hydrocarbon contamination	Water vapour content

NOTE Requirements for oxygen-enriched air are given in ISO 10083

Measuring instrument(s) used ______________________

Manufacturer's Representative

Position ______________________ Signature ______________________

Date ______________________ Name ______________________

Authorized Person

Position ______________________ Signature ______________________

Date ______________________ Name ______________________

Form D.28 — Filling with specific gas

Healthcare facility ____________________ Area identification ____________________

COMPLETE INSTALLATION (Sheet of sheets)

This is to certify that the following medical gas pipelines have been filled with the specific gas as follows

Medical gas	Filling	Flow from all terminal units observed

Manufacturer's Representative

Position ____________________ Signature ____________________

Date ____________________ Name ____________________

Authorized Person

Position ____________________ Signature ____________________

Date ____________________ Name ____________________

Form D.21.1 — Tests for gas identity using an oxygen analyser

Healthcare facility____________________ Area identification ____________________

COMPLETE INSTALLATION *(Sheet .... of .... sheets)*

This is to certify that the identity of the gas at all terminal units has been checked as follows:

Medical gas	**Nominal O_2 concentration** **%**	**Measured O_2 concentration** **%**
Medical air	21	
Oxygen	100	
Oxygen-nitrous oxide mixture	(as specified)	
Oxygen-enriched air	(in accordance with specification)	
Air for driving surgical tools	21	

Measuring instrument(s) used ______________________________

Manufacturer's Representative

Position____________________ Signature____________________

Date ____________________ Name ____________________

Authorized Person

Position____________________ Signature____________________

Date ____________________ Name ____________________

Annex F
(informative)

Risk management checklist

F.1 General

Risk management should be carried out in accordance with ISO 14971.

This annex gives the recommended risk management procedure and checklist used to identify the root causes and hazardous situations (i.e. cause of harm) related to defined safety objectives and appropriate risk control measures for medical gas pipeline systems.

The risk management procedure and the risk control checklist should be used by both the manufacturer (M) of the medical gas pipeline system and the healthcare facility (H) representative(s) during

— design, installation, commissioning and operation of new medical gas pipeline systems,

— ongoing operation and monitoring of existing medical gas pipeline systems.

F.2 Risk management procedure

When managing the risks associated with medical gas pipeline systems, it is first necessary to complete a risk assessment of the overall system.

Having assessed the risks (i.e. the combination of severity and probability of occurrence of the harm), the design should endeavour to mitigate the risks by using procedures in the following order of priority

1) inherently safe design;

2) protective measures in the medical device itself or in the manufacturing process,

3) information for safety.

F.3 Risk management checklist

Table F.1 [1] gives a list of typical safety objectives, root causes, hazardous situations and appropriate risk control measures to mitigate the risk to acceptable levels. It also identifies the organizations responsible for action.

---

[1] In Table F.1, MGPS means Medical Gas Pipeline System.

Table F.1 — Risk management checklist

Safety objective	Root cause	Hazardous situation	Risk control measures	Responsible organizations
1) **Continuity of supply**	a) Partial or complete blockage of the pipeline	Loss or reduction of supply to the patient or equipment	Flow and pressure drop tests at every terminal unit before use	M
	b) Loss of supply from the source of supply in operation	System supplied from the reserve/emergency source if primary source fails Loss of supply to terminal units if all systems fail	Ensure reserve and emergency sources of supply are included in the design of the supply system	H+M
			Ensure reserve and emergency sources of supply are included in the capacity and location of the supply sources	H
			Stock management system established	H
			Preventive maintenance system set up for each source of supply	H
			Operational procedures established to supply cylinders for emergency situations to ensure continuity of supply	H
			Procedures established to minimize use of gases in emergency situations	H
			Routine testing of the reserve and emergency sources of supply to ensure that they will function when primary source of supply fails	H
			Routine testing of the alarm system	H
			Operational Management Document to address failure of supply	H

Table F.1 (*continued*)

Safety objective	Root cause	Hazardous situation	Risk control measures	Responsible organizations
	c) Catastrophic failure of the pipeline	Total loss of supply to terminal units Loss of supply to patient and/or equipment	Design pipeline route to limit areas of high risk to the pipeline	H+M
			Design pipeline routing to limit pipeline corrosion	M
			Design supply systems to prevent mechanical damage	H+M
			Support pipelines to provide adequate support/protection and to limit corrosion	M
			Design components in direct contact with the pipelines to minimize electrolytic corrosion	M
			Earthing of pipeline system to limit electrolytic corrosion	M
			Identify location of pipeline routes Use of markers above pipeline to indicate presence of pipeline in underground ducts, etc.	M
			Protect pipes in high risk areas	H
			Permit to work system	H
			Location of the sources of supply relative to the usage areas	H+M
			Emergency plans for areas with high-dependency patients	H
			Use of emergency local sources of supply adjacent to the usage points	H
			Use of emergency inlet points near area shut-off valves	H
			Routine testing of the alarm system	H
			Operational Management Document addresses issues of pipeline supply failure	H

Table F.1 (*continued*)

Safety objective	Root cause	Hazardous situation	Risk control measures	Responsible organizations
	d) Gas supplier difficulties (Force majeur, e.g. road traffic accident)	Late delivery of liquid or cylinder gases Supplier unable to deliver product in an emergency Supplier with insufficient stocks of cylinders or delivery tank too small	Selection of gas supplier using risk management principles	H
			Appropriate sizing of the storage tank	H+M
			Use of telemetry on storage tanks	H
			Adequate stock management and reordering systems established	H
			Adequate number of cylinders held on site	H
			Appropriate location of cylinder storage areas	H
			Personnel trained to change cylinders on manifolds	H
			Emergency plan	H
			Routine review of delivery planning	H
			Routine review of the stock of the source of supply	H
			Operational Management Document addresses issues of supply failure	H
	e) Late ordering of liquid or cylinder gases	Healthcare facility stock level management inadequate	Routine review of the stock of the source of supply	H

Table F.1 (*continued*)

Safety objective	Root cause	Hazardous situation	Risk control measures	Responsible organizations
	e) Incorrect design/ specification of sources of supply	Failure of supply Inadequate supply to pipeline	Provide usage information	H
			Correct design and sizing of sources of supply based on usage information and supplier's capabilities/contractual arrangements	M
			Design validation in accordance with Clause 12	M
			Commissioning checks following installation	H+M
			Operational Management Document addresses periodic checks of sources of supply installation, layout and access	H
			Operational Management Document addresses periodic checks of usage to review the supply source capability	H
	f) Leakage from pipework	Potential fire risk Potential risk of asphyxiation Potential risk of high concentrations of gases Potential inadequate/ reduced supply to terminal units	Commissioning of the system	H+M
			Operational Management Document addresses periodic checks for leakage from MGPS	H
			Operational Management Document addresses periodic maintenance of MGPS	H

Table F.1 (*continued*)

Safety objective	**Root cause**	**Hazardous situation**	**Risk control measures**	**Responsible organizations**
3) Quality of gas supplied to patient	a) Wrong specification supplied to the supply source	Gas delivered or manufactured on site not complying with specification Gas supplied to the patient not to the correct specification Wrong cylinders/mobile cryogenic tanks supplied/connected to the manifold Gas supplied at the wrong pressure	Certified product supplied by gas supplier	H
			Correct contractual arrangements with the gas supplier	H
			Check for correct connection of flexible connections to the manifold (gas-specific connection where possible)	H+M
			Check that the correct labels are fitted to terminal outlets and area shut-off valves	H+M
			Check that the correct signs are fitted to manifold rooms, cryogenic tanks and medical gas cylinder stores	H+M
			Check that pipelines are marked for the correct gas	H+M
			Operational Management Document to identify the Pharmacist/QC responsibilities	H
			Correct design of gas mixing/manufacturing processes done on site	M
			Commissioning of gas mixing/manufacturing processes done on site	H+M
			Operational Management Document to identify correct maintenance of gas mixing/manufacturing processes run on site	H
			Operational Management Document to identify correct testing of gas mixed/manufactured on site	H
			Operational Management Document to specify the correct procedures for connecting supply source to manifold	H+M
			Operational Management Document to review quality requirements for gases supplied on site	H
			Operational Management document to specify that adaptors should not be used	H
			Operational Management document to specify that transfilling from a large cylinder into smaller one(s) should not be done and that cryogenic liquid transfilling should be done in accordance with the equipment manufacturer's instructions	H

Table F.1 (*continued*)

Safety objective	Root cause	Hazardous situation	Risk control measures	Responsible organizations
	b) Contamination of gases	Gases contaminated by components not cleaned to an appropriate standard Cleaning agent left in component or pipelines Post-construction purging not complying with specification Contamination from compressors/vacuum pumps/oxygen concentrators	Correct procedures to achieve the correct level of cleanliness to ensure proper cleaning and purging	M
			Correct testing procedures identified to demonstrate that conditioning systems are operating correctly	H+M
			Commissioning of the MGPS to ensure the correct cleaning/purging standard	H+M
			Operational Management Document to identify correct cleaning procedures and testing requirements	H
			Operational Management Document to identify correct maintenance of gas compressors/vacuum pumps	H
			Operational Management Document to identify correct testing procedures for possible contaminants in medical air	H
			Correct procedure for validating cleanliness of components used within the MGPS	H+M
			Use components complying with the cleanliness requirements in this part of ISO 7396 Correct location of intake to air compressor(s)	H+M
			Correct functioning of air purification unit/sieve bed	H

Table F.1 *(continued)*

Safety objective	Root cause	Hazardous situation	Risk control measures	Responsible organizations
	c) Excessive particulates in MGPS	Blockage of filters used on components of the system leading to reduced flow Failure of components (regulators, etc.) Leakage of gas through components or connections Wrong functioning of air purification unit/sieve bed	Correct procedure and specification of the cleaning pipework and components and for checking filters after commissioning	M
			Correct testing procedures identified to demonstrate that filters are not blocked (and that there is not excessive particulate in system)	M
			Operational Management Document to identify correct filter cleaning/replacement procedures and testing requirements for MGPS filters	H
			Operational Management Document to identify correct filter cleaning/replacement procedures and testing requirements for medical device filters connected to the MGPS	H
			Operational Management Document to identify correct maintenance of filters	H
	d) Ignition/ decomposition of components used in the MGPS	Toxic gases released into the gas stream	Check that all components used are in compliance with ISO 15001	M
			Operational Management Document to ensure that all replacement parts used on the MGPS are in compliance with ISO 15001	H
	e) Backfeeding of gases within an MGPS	Potential loss of supply to the patient Potential contamination of the supply source or the gas supplied to the patient	Correct design of the MGPS to prevent backfeeding of gases	M
			Commissioning checks to demonstrate performance of any backflow protection devices or differential pressure settings	H+M
			Operational Management Document to identify correct testing and maintenance of backflow protection devices and differential pressure settings	H
	f) Supply of the wrong medical gas	Potential risk of asphyxiation	Operational Management Document to forbid the use of adaptors	H
			Ensure that there is no back flow in medical devices connected to the MGPS	H
	g) Cross-connections between MGPSs	Contamination of the supply source or of the gas supplied to the patient	Correct design of MGPS to prevent cross-connections	M
			Commissioning of MGPS to demonstrate no cross-connections	H+M
			Operational Management Document addresses control of cross-contamination when system is modified/extended	H

G.3.4.6 The AP is responsible for assessing the competency of all CPs and DPs employed directly by the engineering department.

G.3.4.7 The AP is responsible for ensuring that work is carried out only by trained staff or by approved specialist contractors certified to ISO 13485 [15] for regulatory purposes and to ISO 9001:2000 [13] for quality management purposes. The scope of the certification should be defined as design, installation, commissioning or maintenance of the MGPS, as appropriate. Evidence of current certification should be demonstrated by currently valid certification.

G.3.4.8 The AP is responsible for coordinating the different instruction manuals for each individual section of the MGPS to prepare an instruction manual to cover the complete system.

G.3.4.9 The AP should be consulted prior to the purchase of any medical equipment that will be connected to the MGPS to ensure that the design specifications of the MGPS can still be met with the use of the new equipment.

G.3.5 Competent Person (CP)

G.3.5.1 The CP should have sufficient technical knowledge, training and experience to carry out his duties in a competent manner and understand fully the hazards involved with the operation of the MGPS. The CP should be named on the register of competent persons maintained by the FEM.

G.3.5.2 The CP is normally the maintenance person or installer who carries out any work on the MGPS. A list of his responsibilities and duties is set out in G.5.4, "Permit to work procedure".

G.3.5.3 The CP might be a member of a specialist contractor's staff or might be a member of the healthcare facility's engineering department. Where the CP is a member of the engineering department, the AP is responsible for assessing the competency of the CP with respect to work on the MGPS. Where the CP is a member of a contractor's staff, the contractor is responsible for assessing his competence and maintaining a register of CPs within his employment.

G.3.6 Quality Controller (QC)

G.3.6.1 The QC should be appointed in writing by the EM and should be responsible for the quality of the medical gases distributed by the MGPS. The QC might be a pharmacist and should be a suitably qualified person and have specialist knowledge, training and experience of MGPSs.

Where the QC's duties include carrying out specific quality tests on the medical gases distributed by the MGPS, the tests should be in accordance with the documented procedures to ensure that they comply with the relevant specifications.

G.3.6.2 The person designated as the QC (such as a pharmacist) is responsible for the quality control of the medicinal gases distributed by the MGPS at all terminal units and administered to patients to ensure that they conform to the relevant pharmacopoeia specifications. The AP will need to liaise with the QC before an MGPS can be put into use for the first time or after any maintenance or modification to the MGPS to ensure that the medical gas is of the correct quality.

G.3.6.3 The QC should have received adequate training to enable the verification of the quality of medical gas distributed by the MGPS prior to its being put into service. He should also be familiar with the requirements of this annex.

G.3.6.4 The QC should also be responsible for ensuring that the MGPS can continuously deliver medical gas of the correct quality to all patients. This applies especially to medical air supplied by compressor systems or by proportioning systems and oxygen-enriched air produced by oxygen concentrator systems, where the gases are manufactured on site. It can be appropriate to include a medical product quality warning system within the pharmacy department. Regional or national regulations relating to those gases generated on site can exist.

G.3.7 Designated Medical Officer (DMO)

G.3.7.1 The DMO should act as the focal point for all communications between the engineering department and the specific clinical department related to the MGPS. The DMOs should be defined in the Operational Management Document.

G.3.7.2 The DMO should advise the engineering department of any special requirements for his department relating to the MGPS, such as provision of emergency cylinders.

G.3.7.3 The DMO is the medical person who should be consulted on pipeline extensions and other modifications to the MGPS. The DMO should be responsible for informing the AP of any significant changes in the usage of medical gases or the introduction of new clinical procedures which can affect the medical gas demand.

G.3.8 Designated Nursing Officer (DNO)

G.3.8.1 The DNO should act as the focal point for all communications related to the MGPS between the engineering department and his own specified department or departments. There would ideally be a DNO in each department and they should be defined in the Operational Management Document.

G.3.8.2 The DNO is the appointed person in each department with whom the AP liaises on any matters affecting the MGPS and who should be responsible for giving permission for a planned interruption to the supply.

G.3.8.3 When the DNO gives permission for any interruption to the MGPS in a specified department or departments, he should sign the appropriate part of the "Permit to Work". The Operational Management Document should clearly set out the requirements for such permission.

The AP should describe to the DNO the extent to which the MGPS will be restricted or interrupted while any work is in progress and should indicate the level of hazard involved. The DNO should assist, as necessary, to ensure that service is maintained whilst the MGPS is disrupted.

G.3.8.4 The DNO is responsible for ensuring that the relevant staff in the department are made aware of the interruption to the MGPS and which terminal units cannot be used.

G.3.8.5 The Operational Management Document should list the DNOs for each department and any arrangements for coverage during their absence.

G.3.8.6 The DNO should carry out the appropriate action in the event of an emergency as detailed in the Operational Management Document.

G.3.8.7 All DNOs should be trained in the use of the MGPSs relevant to their departments and on the action to be taken in the event of an emergency.

The Operational Management Document should set out these training requirements.

G.3.9 Designated Person (DP)

G.3.9.1 The DP should be a suitably trained person. He should be given the responsibility of carrying out particular operations on the MGPS (e.g. changing cylinders on the MGPS manifold, testing alarm systems, etc.).

G.4 Operational Management Document

G.4.1 The operational management requirements for operating the MGPS should be detailed in an Operational Management Document.

This annex can be used to develop an Operational Management Document.

G.4.2 The Operational Management Document should include documented procedures for the following:

a) control of documents and records;

b) training and communication;

c) emergency management;

d) change management;

e) permits to work;

f) preventive maintenance;

g) repair;

h) sources of supply management;

i) cylinder storage and handling;

j) medical equipment purchase;

k) contractors management.

NOTE Separate policies or procedures are sometimes prepared to supplement the Operational Management Document.

G.4.3 The EM is responsible for the overall Operational Management Document and its implementation.

G.4.4 The Operational Management Document should state the procedures to be followed and the personnel who need to be consulted before a new item of medical equipment is connected to the MGPS. Special attention should be paid to changes of the supply system or to the introduction of an oxygen concentrator system for supplying gas to the MGPS.

It is especially important that set points on alarm systems be reviewed prior to using the system.

G.4.5 In some areas of the facility, medical gas equipment can be installed within enclosures or behind decorative panels in order to provide a more domestic environment. In these cases, it is essential that identification is maintained so that staff are aware that equipment is available for patient use.

Where gas blenders (mixers) are used, the manufacturer's instructions should be followed with regard to operation and maintenance to prevent back feeding of one gas into the other pipeline in the event of equipment malfunction.

NOTE Some older types of blending equipment can allow the backflow of gas from one pipeline to another, which can lead to oxygen enrichment of medical air systems, or reduction of the oxygen concentration in oxygen pipelines

G.5 Operational procedures

G.5.1 Procedure for control of documents and records

G.5.1.1 The Operational Management Documents should be controlled by the quality management system to ensure that the relevant and latest versions of applicable documents are available at the point of use.

The procedure should define the controls needed to

- review and approve documents,
- ensure that only the current versions of applicable documents are available at points of use,
- prevent the unintended use of obsolete documents.

G.5.1.2 All records of results of the activities carried out in accordance with the procedures in the Operational Management Document should be retained.

NOTE Subclauses 4.2.3 and 4.2.4 of ISO 13485:2003 [15] give guidelines for control of documents and records.

G.5.1.3 The EM is responsible for monitoring the Operational Management Document to ensure that it is being properly implemented. This should be carried out on a regular basis, and the procedure for such monitoring should be set out in the Operational Management Document.

G.5.1.4 The responsibility for monitoring specific aspects should be delegated to the appropriate key personnel. The details of such delegation should be set out in the Operational Management Document.

G.5.2 Training and communication procedure

G.5.2.1 All personnel involved in the administration and use of medical gases in the healthcare facility should have a sound general knowledge of the operational principles, basic design and functions of the MGPS. They should be trained on those specific systems for which they will be responsible.

G.5.2.2 A training programme should be established for all staff responsible for the operation and use of the MGPS. This should include any nursing staff. All training should be recorded and reviewed regularly.

G.5.2.3 All APs, DPs and CPs should have satisfactorily completed an appropriate training course before they are appointed.

G.5.2.4 All APs, DPs or CPs should have sufficient experience, be familiar with their particular installations and have their competency assessed before they are appointed.

G.5.2.5 It is recommended that all APs have their training re-assessed at set intervals and attend a refresher or other training course prior to the reassessment. The recommendation for appointment or re-appointment as an AP should be made by a FEM who has specialist knowledge of the MGPS.

G.5.2.6 The QC should receive specific training covering the responsibilities and duties which he will be required to carry out with respect to the MGPS. It can be appropriate for the QC to attend part or all of the training courses for APs.

G.5.2.7 The medical and nursing staff who use the MGPS should be trained in the use of the system. This training should include practical use of the system and emergency and safety procedures. The EM should ensure that all staff have received this training prior to using the MGPS and that refresher courses are arranged.

G.5.6 Preventive maintenance procedure

G.5.6.1 All maintenance activities should be carried out in accordance with the technical specifications supplied by the manufacturer(s) of the MGPS.

G.5.6.2 A systematic approach to the preventive maintenance of a medical gas pipeline system is essential. This annex provides information that should be used when setting up a preventive maintenance programme, but does not include actual maintenance tasks or frequencies of maintenance.

G.5.6.3 MGPSs should be subjected to planned preventive maintenance and this should be the responsibility of the AP.

G.5.6.4 All preventive maintenance work carried out on the MGPS, whether or not the supply is, or is likely to be, interrupted, should be carried out only under the instructions of the AP. When unplanned maintenance work is necessary, it should be carried out only with the prior permission of the AP.

G.5.6.5 The Operational Management Document should clearly set out the responsibilities and the procedures to be followed for all maintenance work on the MGPS.

G.5.6.6 A permit to work should be issued prior to any planned preventive maintenance work being carried out on an MGPS. This includes all examinations where no interruption to the service is anticipated. Where unplanned emergency work is carried out, where it might not be practicable to raise a permit, the work should be carried out under the direct supervision of the AP.

G.5.6.7 Inspection and maintenance work should be carried out by appropriately trained and qualified personnel.

G.5.6.8 The AP should be responsible for monitoring the maintenance work, including any work carried out by contractors. It can be appropriate to arrange site meetings, when necessary, with the contractor's representatives to discuss progress.

G.5.6.9 All maintenance work on the MGPS carried out by a contractor should be covered by a formal contract.

G.5.6.10 The contractor should be instructed in the healthcare facility's safety procedures and confirm that he will comply with the requirements at all times.

G.5.6.11 All contractor's staff should report to the AP upon arrival on site and prior to leaving the premises. Contractor's staff should not visit the location of supply plant and distribution equipment without prior permission of the AP.

G.5.6.12 The contractor is responsible for ensuring that the staff working on any part of the MGPS are appropriately trained and qualified to carry out the work. The healthcare facility should not be required to test the competency of contractor's staff.

G.5.6.13 The preventive maintenance plan should include method statements for each specific task, the recommended frequency of the task, and any records required to be maintained for each identified task. The method statement should be applicable to the actual plant and equipment installed on site and should be in conformance with the manufacturer's instructions. The preventive maintenance plan should also define who is responsible for the work.

G.5.6.14 A maintenance log should be maintained for each plant item. The maintenance log should be updated following each planned maintenance job or following any non-planned work carried out. It can be appropriate to define the maintenance status on each plant item, providing the date the work was last carried out and the date of the next planned service.

G.5.6.15 In order to ensure that the maintenance service is being carried out in accordance with the contract, the healthcare facility should monitor the work and the performance of the contractor. The AP should be responsible for the satisfactory implementation of the maintenance contract.

G.5.6.16 The AP should prepare an inspection checklist, to be carried out and documented daily, to demonstrate that the MGPS is functioning correctly. The checklist should be based on the inspection routines specified by the manufacturer.

G.5.6.17 The preventive maintenance plan should take into account the manufacturer's recommendations concerning service requirements and maintenance instructions.

Particular attention should be paid to

a) the performance of the system and its components,

b) leakage of gas,

c) excessive wear of any components,

d) the quality of the gas.

A procedure for immediately reporting defective or suspect equipment to the AP should be established to allow its prompt repair or replacement.

G.5.6.18 The healthcare facility should ensure that adequate spare parts are readily available, as recommended by the manufacturer(s).

G.5.6.19 The manufacturer(s) of the MGPS should provide the healthcare facility complete as-built drawings of the MGPS, maintenance instructions for all components, associated circuit diagrams and any valve charts.

G.5.6.20 The frequency of maintenance of components in the preventive maintenance plan should be based on information detailed in the manuals for the equipment and components installed. Practical experience with equipment from different manufacturers, and information from plant history logs, might result in the need to vary some frequencies and tasks in particular installations.

G.5.6.21 In addition to the examination, tests and checks set out in the preventive maintenance plan, arrangements should be made for a general overhaul of all MGPSs in conjunction with the manufacturer's recommended frequency.

G.5.6.22 The preventive maintenance plan should include functional testing of the backup supply systems and the alarm systems to ensure that they will operate when required.

The maintenance log should be reviewed regularly by the AP to identify any components or equipment that are requiring excessive attention caused by faulty design or by unsatisfactory conditions of any nature. Maintenance tasks and their frequency should be modified in line with the information detailed in the maintenance log.

G.5.6.23 Equipment checklists should be prepared. Area shut-off valves and line pressure regulators should be referred to in the checklist by a unique number which corresponds with the valve tag number. It is usually convenient to arrange these checklists in such a manner that a record can be made for each valve showing whether it has been examined, tested or checked in accordance with the preventive maintenance plan.

G.5.6.24 Following any maintenance activity, the appropriate tests in accordance with Clause 12 of this part of ISO 7396 should be carried out.

G.5.6.25 Any instruments used in the maintenance and testing of any equipment associated with the MGPS should be calibrated against an appropriate standard and the results logged.

G.5.6.26 No section of the MGPS should be worked on or pressure tested unless it is adequately isolated from any section in use or available for use.

G.5.8.12 The use of telemetry systems fitted to the installation permits both the healthcare facility and the gas supplier to monitor the stock levels, permitting more efficient use of the operational stock and allowing for a smaller reserve stock.

G.5.8.13 The reserve stock should be expressed as the number of days of stock. When the daily demand increases, the required volume will grow, reducing the volume of operational stock available.

G.5.8.14 The minimum level for reserve stock for the secondary supply should be based on the exceptional circumstances when the primary supply system is not available for use.

This secondary supply reserve stock level will depend on

— the proximity of the supplier's distribution depot,

— the time that the gas supplier needs to make a delivery under these conditions,

— the delivery frequency that can be sustained when the primary supply is unavailable for use.

G.5.8.15 Under most conditions, compressed gas cylinders are the most appropriate method of providing a reserve source of supply. The preferable solution for the design of reserve systems is to install individual manifolds on each zone of the pipeline system, to provide for the additional protection against the possibility of a pipeline failure within the facility. The positioning of these manifolds is very important to ensure that the critical supply and high-dependency areas defined in the risk management process have adequate stocks of medical gases available in the event of a MGPS failure.

G.5.8.16 In critical care areas with high-dependency patients, the healthcare facility should consider the use of individual cylinders to minimize any delay in maintaining gas supplies in an emergency. Cylinders with integral valves or cylinders with pressure regulators attached should be used for this purpose: the pressure regulator outlet should be gas-specific and connected to a low-pressure hose assembly.

G.5.8.17 Where medical gases are manufactured or mixed on site, they are subject to the same regulations or standards as for gases supplied by other sources. In particular, the principles of good manufacturing practices apply.

G.5.8.18 Where supply systems for oxygen-enriched air are installed, medical staff should take into account the reduced oxygen concentration and be aware of possible increases in concentration if medical oxygen is used in the secondary and/or reserve supply system.

G.5.8.19 The functionality of the secondary and reserve sources of supply should be tested using a defined procedure at regular intervals and the results documented in the maintenance log. Following the tests, the condition of the secondary and reserve sources should be reviewed and additional supplies provided where appropriate. The test procedures should take into account the specifications defined by the manufacturer and approved by the AP.

G.5.8.20 The alarm system on the medical gas supply systems should be tested at regular intervals according to a defined procedure and the results documented in the maintenance log. The test procedures for the alarm system should take into account the specifications defined by the manufacturer and approved by the AP.

G.5.9 Cylinder storage and handling procedures

G.5.9.1 The cylinder storage and handling procedures should cover the operational aspects of all medical gas cylinders used within the healthcare facility, including the requirements for storage, handling and general safety.

G.5.9.2 Management of medical gas cylinders within the healthcare facility should be the responsibility of the AP or the QC and defined in the Operational Management Document. Only trained and approved persons should be permitted to handle and/or connect cylinders to the manifold.

G.5.9.3 Medical gas cylinders should be stored in a medical gas cylinder storage area, either in a designated storeroom which is part of the healthcare facility building or in a separate, specially constructed cylinder storage building. The area should be used exclusively for medical gas cylinder storage. These cylinder stores should be under cover, provided with adequate ventilation and should be protected from theft and unauthorized use. They should not be located in close proximity to any installation which can present a fire risk or other hazard. Smoking and naked flames should be prohibited in the vicinity. Plant rooms containing medical gas cylinders should be kept locked, with a prominently displayed notice indicating the location of the key.

G.5.9.4 The use of adapters with medical gas cylinders is strongly discouraged due to the risk of administering the wrong gas to the patient.

G.5.9.5 Due to the hazards related to filling high-pressure cylinders, the need to carry out the transfilling procedures under good manufacturing practice conditions and the requirement to maintain traceability of all medicinal products, transfilling of medical gas cylinders is strongly discouraged.

G.5.9.6 The cylinder storage areas should segregate medical and industrial gas cylinders.

Medical gas cylinders should be stored so that there is segregation of full and empty cylinders and of cylinders of different gases.

NOTE The requirements for separation requirements/distances between different types of gases are defined by local regulations or by industrial guidelines.

G.5.9.7 Medical gas cylinders should be managed so that they are used on a first-in, first-out basis to ensure correct stock rotation. The tamper-evident seals fitted to the valve outlets should be retained until the cylinder is required for use.

G.5.9.8 The AP should be aware of the hazards related to the storage, transport and use of gas cylinders. The gas cylinder supplier is responsible for supplying the healthcare facility with adequate information on the safe use and handling of all cylinders.

G.5.9.9 The requirements for storing medical gas cylinders apply to both the main cylinder storage areas and any in-use storage of cylinders in wards or in the vicinity of a manifold connected to the MGPS.

G.5.9.10 Safety warning signs and notices should be used where appropriate and posted in prominent positions.

G.5.9.11 Cylinder stores should be located as close as possible to the delivery point. Wherever possible, there should be only one delivery supply point for each site. Vehicle parking, other than for loading and unloading cylinders, should not be permitted within the delivery and storage area.

G.5.9.12 The location of the cylinder storage area should be marked clearly on the site plan for ease of identification in the event of an emergency.

G.5.9.13 Cylinders should only be handled by personnel who have been trained in cylinder handling and who understand the potential hazards. Only specifically designed and approved equipment should be used for handling and transporting medical gas cylinders.

G.5.9.14 Cylinders and valves should be kept free from oil, grease and other debris. The cylinder valve outlet should be inspected for evidence of oil, grease and other debris before being connected to the manifold or a pressure regulator. Cylinders with evidence of contaminated valve outlets should be labelled as such and returned to the cylinder supplier.

G.5.9.15 Where proprietary leak detection fluids are used to detect leaks between the cylinder valve and the manifold, they should be used sparingly and any excess should be wiped off with a clean damp cloth after use to avoid possible contamination. Proprietary leak detection fluids should not be used for leak testing cylinder valve outlets.

G.5.9.16 Excessive force should not be used when connecting a manifold or a pressure regulator to the cylinder valve, as this can damage the valve outlet. If a leak is detected between the cylinder valve and the manifold or the pressure regulator, the manifold or the pressure regulator should be depressurized and the cylinder removed. The fitted seal should be inspected and replaced if necessary. Sealing of jointing compounds should never be used to cure a leak.

G.5.9.17 The Operational Management Document should cover the control and removal of defective equipment to prevent them from being used with high-pressure cylinders. Faulty cylinders should be labelled and returned to the cylinder supplier.

G.5.9.18 Repairs to cylinder valves should not be carried out under any circumstances. If a fault with the cylinder valve is suspected, the cylinder should be labelled as such and immediately returned to the cylinder supplier.

G.5.9.19 Local regulations applying to general fire precautions related to the storage of high-pressure cylinders can exist.

G.5.9.20 All medical equipment used with high-pressure gas cylinders should be subject to planned preventive maintenance. Only equipment designed for use with the specific gas should be used. When the equipment is connected to a cylinder, the cylinder valve should initially be opened slowly and then opened fully.

G.5.9.21 The number of cylinders in manifold rooms should be restricted to the minimum required for operational and reserve purposes. Only cylinders of the gases required for connection to the manifold should be kept in the manifold room. The manifold room should not be used for any other purpose, although an exception can be made for storage of nitrous oxide/oxygen mixture cylinders on trolleys to permit temperature equilibration before use.

G.5.9.22 The main stocks of oxygen, nitrous oxide, medical compressed air and other medical gas cylinders should be stored in the designated cylinder storage area, protected from adverse weather conditions. No other materials should be kept in the cylinder storage area.

G.5.10 Medical equipment purchase procedure

G.5.10.1 The AP should be consulted prior to the purchase of any medical equipment which will be connected to the MGPS. This is to ensure that the MGPS has sufficient capacity and can deliver the required flows at the specified pressures. It is particularly important that the AP be consulted before any new equipment, such as a ventilator, is connected to the medical air system, to ensure that the system capacity is not exceeded.

G.5.10.2 The Operational Management Document should state the procedures to be followed and the personnel who need to be consulted before a new item of medical equipment is connected to the MGPS.

G.5.11 Contractors management procedure

G.5.11.1 The requirements for contractors are different, depending upon the activities to be carried out. Requirements for maintenance and repair activities are lower than those for new pipeline systems, alterations or extensions, which include design, installation and testing.

G.5.11.2 All contractors should comply with the healthcare facility's safety policies. This should be clearly stated in the Operational Management Document.

G.5.11.3 Work on MGPSs should only be carried out by trained staff or by specialist firms certified to ISO 13485 [15] with scope of certification defined as design, installation, commissioning and maintenance of MGPS as appropriate. Evidence of current certification should be demonstrated by currently valid certificates.

G.5.11.4 The Operational Management Document should set out the responsibilities for monitoring the work of contractors. This should be co-ordinated by the AP. The procedures for calling out a contractor, in the event of a single fault or an emergency, should be set out in the Operational Management Document.

Annex H
(informative)

Rationale

The numbering of the following rationale corresponds to the numbering of the clauses in this part of ISO 7396. The numbering is, therefore, not consecutive.

H.1 In some countries where bulk medical liquid oxygen is not readily available, oxygen concentrators can be used for supplying oxygen-enriched air to a medical gas pipeline system as a substitute for medical oxygen. As oxygen-enriched air is not covered by a pharmacopoeia monograph in all territories, regional or national regulations might prevent its use as a replacement for medical oxygen.

Where oxygen concentrators are used, medical oxygen cylinders are often used as the secondary or reserve source to supply the pipeline system in the event of failure of the concentrator. As this could lead to significant variation in the characteristics of the gas administered to the patient, consideration should be given to using dedicated terminal units and connectors which are gas-specific for oxygen-enriched air. In addition, flow-metering devices and gas mixers used should be specifically calibrated for the range of oxygen concentrations produced by the concentrator and adjustments made when medical oxygen is used. The healthcare facility should have a well-documented emergency plan to indicate the appropriate actions which should be taken when changing the source of supply to ensure that there is no risk to the patient.

If an oxygen concentrator is used to supply oxygen-enriched air to the medical gas pipeline system, the manufacturing process should be controlled by a suitable quality management system which is compliant with the principles of good manufacturing practice (GMP). It should be the responsibility of the healthcare facility pharmacist to ensure that the plant is operated correctly and that the quality of the gas is suitable for its intended use. Where the plant is used for the filling of oxygen-enriched air cylinders for use as a secondary or reserve source or as free-standing cylinders, the process of filling should also be covered by the principles of GMP. It can also be necessary to comply with other pressure system legislation to demonstrate that the cylinders are suitable for filling and that they are not subjected to conditions outside their design range. Batch records should be maintained to ensure there is traceability of the product.

Experience with the use of oxygen concentrators supplying medical gas pipeline systems is increasing and, therefore, it can be considered as a useful and safe alternative for oxygen in the future. The purpose of this part of ISO 7396 is to specify the characteristics of the medical gas pipeline system suitable for use with oxygen-enriched air produced by oxygen concentrators complying with ISO 10083 where their use is permitted by regional or national regulations.

The requirements for flow, pressure and storage capacity for compressed air used to pressurize hyperbaric chambers, to maintain the required internal environmental conditions and to drive other connected services (e.g. the fire extinguishing system) are different from those specified in this part of ISO 7396 for medical air and for air for driving surgical tools.

H.4.1 A fault condition can remain undetected for a long period of time and, as a consequence, can lead to a catastrophic event. Such a fault condition cannot be considered as a single fault condition. Specific risk control measures should be determined within the risk management process to deal with such conditions.

H.4.2 Evidence will be provided, for example, to a notified body during conformity assessment and upon request to the competent authority. Attention is drawn to ISO 14971 on risk management and to the standards under development by ISO/TC 210 on risk evaluation and risk control.

H.4.3.2 Components of the pipeline system for different gases are often made with interchangeable parts or subassemblies. The requirement for cleanliness should, therefore, be applied to components for all gases.

H.4.3.1, 4.3.2, 4.3.4, 4.3.5, 4.3.6, 4.3.8 Evidence will be provided, for example, to a notified body during conformity assessment and to the competent authority upon request.

H.5.3.5 Ignition of polymer-lined high-pressure flexible hoses is known to have occurred in several countries (e.g. as a result of adiabatic compression). Decomposition of certain polymers can occur at temperatures which can be produced by adiabatic compression. The products of decomposition and combustion of some polymers are known to be extremely toxic. The use of polymer-lined flexible hoses is, therefore, not permitted.

H.5.5.1.2 The devices and systems listed in 5.5.1.2 are not used to supply medical air to patients and might not be subject to the cleanliness requirements of medical gas pipeline systems. Therefore, it is essential to prevent backflow to avoid contamination of the pipelines for medical air.

H.5.5.2.1 and **5.5.2.3** Experience from several countries over many years has shown that the specifications given in these clauses are adequate for medical air and for air for driving surgical tools, provided that the supply system is properly maintained. A monograph on medical air has been published by the European Pharmacopoeia Commission (EPC) [27].

H.5.8 Low temperatures can result in pressure loss in cylinders of nitrous oxide and carbon dioxide. Low temperatures can also cause liquefaction of the nitrous oxide in cylinders of oxygen/nitrous oxide mixtures, resulting in the supply of a gas mixture of incorrect composition. High temperatures can result in high pressures and possible loss of gas from cylinders fitted with means of pressure relief. High temperatures can cause malfunctioning of air compressors and vacuum pumps.

H.6.2.3 Electrical power connections for the monitoring and alarm systems require a degree of separation from other electrical circuits.

H.6.3.2.4 The maximum silencing period of 15 min is appropriate because equipment in critical areas such as patient monitors, life-support intensive care ventilators and anaesthetic workstations are themselves recycling high priority alarms at shorter intervals.

H.6.6 In some countries, the sensors for emergency operating alarms are specified to be upstream of the supply shut-off valve, and in other countries, the sensors are specified to be downstream of the supply shut-off valve. The subcommittee heard persuasive arguments for both locations.

H.7.2.5, 7.2.6 Evidence will be provided, for example, to a notified body during conformity assessment and to the competent authority upon request. Bursting discs are not permitted as a means of pressure relief since their operation can lead to complete loss of pressure in a pipeline.

H.7.4.1 Subclause 5.2.2 mandates continuity of supply to the terminal units in normal condition and in single fault condition. Two permanently connected line pressure regulators will allow continuity of supply requirements to be met when one pressure regulator fails.

H.12.6.2 The reason for testing area shut-off valves is that these valves are required to close in an emergency. The equivalent tests of other shut-off valves are impractical.

H.12.6.7 Evidence will be provided, for example, to a notified body during conformity assessment and to the competent authority upon request.

Bibliography

[1] ISO 4126-1, *Safety devices for protection against excessive pressure — Part 1: Safety valves*

[2] ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

[3] ISO 7183, *Compressed air dryers — Specifications and testing*

[4] ISO 7183-2, *Compressed air dryers — Part 2: Performance ratings*

[5] ISO 7396-2, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems*

[6] ISO/TR 7470, *Valve outlets for gas cylinders — List of provisions which are either standardized or in use*

[7] ISO 8573-2, *Compressed air — Part 2: Test methods for oil aerosol content*

[8] ISO 8573-3, *Compressed air — Part 3: Test methods for measurements of humidity*

[9] ISO 8573-4, *Compressed air — Part 4: Test methods for solid particle content*

[10] ISO 8573-5, *Compressed air — Part 5: Test methods for oil vapour and organic solvent content*

[11] ISO 8573-6, *Compressed air — Part 6: Test methods for gaseous contaminant content*

[12] ISO 8573-8, *Compressed air — Part 8: Test methods for solid particle content by mass concentration*

[13] ISO 9001:2000, *Quality management systems — Requirements*

[14] ISO 10524-4, *Pressure regulators for use with medical gases — Part 4: Low-pressure regulators*

[15] ISO 13485:2003, *Medical devices — Quality management systems — Requirements for regulatory purposes*

[16] AS 2896-1998, *Medical gas systems — Installation and testing of non-flammable medical gas pipeline systems*

[17] CAN/CSA-Z305.6-92, *Medical oxygen concentrator central supply system: for use with nonflammable medical gas piping systems*

[18] CGA E-10-2001, *Maintenance of medical gas and vacuum systems in health care facilities*

[19] EN 475, *Medical devices — Electrically-generated alarm signals*

[20] EN 12021, *Respiratory protective devices — Compressed air for breathing apparatus*

[21] EN 13133, *Brazing — Brazer approval*

[22] EN 13134, *Brazing — Procedure approval*

[23] EN 14931, *Pressure vessels for human occupancy (PVHO) — Multi-place pressure chamber systems for hyperbaric therapy — Performance, safety requirements and testing*

[24] FD S 90-155, *Systèmes de distribution pour gaz médicaux comprimés et vide — Compléments pour la conception et la réception ("Pipelines for compressed medical gases and vacuum — Additional elements for design and commissioning")*

[25] HTM 02/01:2006, *Health Technical Memorandum — Medical gas pipeline systems, Part A: Design, installation, validation and certification*

[26] HTM 02/01:2006, *Health Technical Memorandum — Medical gas pipeline systems, Part B: Operational management*

[27] Monograph on *Medical Air*, European Pharmacopoeia Commission, 2005

[28] Monograph on *Synthetic Air*, European Pharmacopoeia Commission, 2005

[29] NFPA 99, *Health Care Facilities*

[30] SIS HB 370, *Säkerhetsnorm för medicinska gasanläggningar*

G.5.6.27 Before any planned preventive or unplanned maintenance work is carried out on any medical equipment, including portable suction units, the equipment should be decontaminated, following approved procedures.

G.5.6.28 The Operational Management Document should define the length of notice which should be given to the DMO and DNOs by the AP before interruption of the MGPS can be made when carrying out planned preventive maintenance. It might not be possible to provide the same notice for any emergency maintenance work carried out on the MGPS.

G.5.7 Repair procedure

G.5.7.1 The repair of any faulty component(s) on the MGPS should be carried out in accordance with the technical specifications supplied by the manufacturer(s) of the MGPS.

G.5.7.2 All repair work on the MGPS should only be carried out under the instructions of the AP, whether or not the supply is, or is likely to be, interrupted.

G.5.7.3 The Operational Management Document should clearly set out the responsibilities and procedures to be followed for all repair work on the MGPS.

G.5.7.4 Repair work should be carried out by appropriately trained and qualified personnel.

G.5.7.5 The AP should be responsible for monitoring the repair work, including any repairs carried out by contractors.

G.5.7.6 All repair work on the MGPS which is carried out by a contractor should be covered by a formal written contract.

G.5.7.7 The contractor is responsible for ensuring that his staff working on any repairs are appropriately trained and qualified to carry out the work. The healthcare facility should not be required to test the competency of the contractor's staff.

G.5.7.8 The results of any action taken to correct faults should be recorded in the maintenance log.

G.5.7.9 Following any repair activity, the appropriate tests in accordance with Clause 12 of this part of ISO 7396 should be carried out and the results recorded in the maintenance log.

G.5.7.10 Any instruments used in the repair and testing of any equipment associated with the MGPS should be calibrated against an appropriate standard and the results recorded in the maintenance log.

G.5.7.11 No section of an MGPS should be worked on or pressure tested unless it is adequately isolated from any section in use or available for use. This requirement should be specified in the permit to work.

G.5.7.12 The AP should report to the FEM any recurring equipment failure or evidence of excessive wear of equipment identified by the DP. The FEM should assess these observations and take the appropriate corrective actions.

G.5.8 Supply sources management procedure

G.5.8.1 The capacity of each supply source used to supply medical gases into the MGPS should be based on the average demand for the healthcare facility, with allowances for any projected growth or reduction in demand over the next five years and any diversity factor, to take account of the variability of demand.

G.5.8.2 The healthcare facility should work together with the medical gas supplier and the system manufacturer to determine the appropriate location of each source of supply, using risk management principles and to ensure that it conforms with the regional or national regulations where required.

G.5.8.3 For medical gases stored on site, the capacity of the supply source should be reviewed regularly to ensure that sufficient product is stored on site to maintain the supply of medical gas to the MGPS. Where it is determined that there is insufficient product stored on site, either the medical gas supplier should agree with the healthcare facility to revise delivery frequencies to maintain the operational stock levels or the capacity of the storage system on site should be increased.

G.5.8.4 Any anticipated increase in demand due to hospital site developments, pipeline extensions or changes in clinical practice should be notified to the medical gas supplier to ensure that the changes do not jeopardize security of supply.

G.5.8.5 The medical gas demand should be reviewed and documented with the gas supplier at least annually (or after a significant extension to the pipeline causing increases in demand) to reassess the capacity of the installation. As the demand grows, the storage volume requirements will increase. With the increased volume requirements for the reserve stock, the volume available for operational stock will be reduced. Having reviewed the average daily demand with the gas supplier, it can be necessary to either revise delivery frequencies to maintain the operational stock levels or to increase the capacity of the storage systems on site.

G.5.8.6 Where available, historic gas consumption records should be reviewed to assess the current usage and the growth or reduction of the medical gas demand. Growth predictions should be based on any planned extensions to the facility or pipeline systems and changes in clinical practices that could impact on the demand for medical gas.

G.5.8.7 For new healthcare facilities, where no historic information is available, the estimated demand should be based on the proposed size and type of the facility and/or, in cases where the new facility is a replacement, the usage figures of the facilities being replaced.

G.5.8.8 Where the secondary supply includes compressed gas cylinders, the size of the change-over manifold and the number of cylinders stored on site should be based on the gas supplier's ability to guarantee delivery within a defined period.

G.5.8.9 There should be an adequate number of trained individuals available to ensure that cylinders can be changed over on the manifold quickly enough to meet the demand.

G.5.8.10 The delivery period for the primary supply should be based on the gas supplier's normal delivery frequency. The delivery period for the secondary supply should be based on emergency conditions when the primary supply is not available. Under these circumstances, special delivery response times should be agreed upon by the gas supplier and should normally not be less than 24 h.

G.5.8.11 The capacity of the primary and secondary supply source should be determined by the risk management process and be specified as a number of days' stock.

The risk assessment should consider the following issues:

— the estimated average daily demand at the end of the contract period. Any changes to the predicted demand will need to be considered and changes made to the tank capacity or delivery frequency at the appropriate time within the contract period. It can be worthwhile to set a daily demand rate at which point changes to tank size or delivery frequency will be considered;

— the delivery frequency should take into account and review vehicle access to the storage vessels, timing of the deliveries and any restrictions due to local planning requirements;

— the capabilities of the medical gas suppliers to provide a reliable supply;

— the type and dependency of the patients being treated in the healthcare facility;

— the variability of the facility's usage pattern, taking into account seasonal variations or the additional requirements for the facility's major incident plan;

— the use of telemetry to electronically relay stock levels to the gas supplier or the healthcare facility.

G.5.2.8 The Operational Management Document should set out the means of communication between the various key personnel. It should define which departments need to be informed of work being carried out on the MGPS, the personnel to be notified and whether such information should be given verbally or in writing.

G.5.2.9 The actions to be taken in the event of a fault with the MGPS should be detailed in the Operational Management Document. There should be a clear means of reporting any faults to the FEM.

G.5.2.10 All staff who are involved in the use, installation or maintenance of the MGPS should be aware of the Operational Management Document and their specific responsibilities within it.

G.5.2.11 The Operational Management Document should detail the need to ensure that

- all users are aware of the capacity and any particular limitations of the MGPS,
- nursing and medical staff are aware of the purpose of alarm systems and the action to be taken in the event of an alarm being activated.

G.5.2.12 Staff responsible for the operation of the MGPS should be aware of

- the activities necessary to ensure the continued safe operation of the system,
- the actions to be taken in a single fault condition or in an emergency situation where the MGPS fails to deliver gases to the terminal units.

NOTE Safety objectives and hazardous situations are given in Annex F.

G.5.3 Emergency procedure

G.5.3.1 The Operational Management Document should set out the procedures to be followed in the event of an emergency. These should include:

a) reporting of all incidents;

b) action(s) to be taken, such as shutting off area shut-off valves, use of portable emergency cylinders, etc.;

c) liaison with other staff and departments;

d) calling out contractors.

G.5.3.2 All national or local regulations relating to fire precautions should be complied with.

G.5.3.3 The emergency procedure set out in the Operational Management Document should be followed.

G.5.3.4 Where an incident is likely to cause an interruption to the supply or affect patient and personnel safety, the contractor responsible for dealing with the emergency affecting the MGPS should specify either a maximum time, from the receipt of the initial call to when the contractor is on site, or the need to provide adequate information for immediate action to be taken.

G.5.3.5 The Operational Management Document should include communication procedures to ensure that any emergency involving the MGPS is communicated immediately to all clinical areas likely to be affected and to all staff involved in the maintenance of gas supplies and in remedial actions.

G.5.3.6 Such communication procedures should include:

- the nature of the emergency;
- details of the gas conservation procedures to be applied;
- likely duration of the emergency;

— remedial actions to be taken;

— the need to record the details of any emergency incidents and related communications.

G.5.3.7 Experienced persons in each area to co-ordinate and communicate actions should be nominated.

G.5.3.8 Regional or national regulations relating to external communications of incidents should be complied with.

G.5.3.9 The DNO should be properly trained in the emergency procedures required to control the medical gases and the MGPS. He should be fully familiar with the location of all area shut-off valves in the specific department(s).

G.5.3.10 Emergency procedures should be initiated at least twice a year as an exercise, and any issues or need for retraining noted and followed up.

G.5.3.11 When the normal power supply is reinstated following a power supply failure, the responsible staff should ensure that all sources of supply are in a suitable condition for use.

G.5.3.12 The engineering department should have accurate and up-to-date drawings of the MGPS showing main sections and branches, departments served, pressure regulators, isolation valves, terminal units and alarm systems for each medical gas service. These drawings should be readily available on site and their location known by all APs.

G.5.3.13 The Operational Management Document should specify the requirements for locking valves and medical gas plant rooms and the procedures for keeping the keys in a safe location. The emergency services should be informed of the location of all keys related to the MGPS.

G.5.3.14 In the event of an emergency such as a fire or a major leak, a trained person should isolate the affected section by closing the emergency isolating valves or area shut-off valve. They should notify the AP and the appropriate DNO immediately.

G.5.3.15 On receiving notification of an emergency, the DNO in each clinical area should control the use of gas from the pipeline system(s) involved to the minimum level required whilst maintaining patient safety.

G.5.3.16 The Operational Management Document should describe the procedures necessary to manage the stocks of gas in the supply system to ensure that there is gas available for use in cases of emergency.

G.5.3.17 The AP should check and ensure that designated trained staff bring into use emergency supplies when required. Sufficient cylinders for use on emergency manifolds or cylinders held in storage for emergency use should be made available, following the appropriate procedures specified in the Operational Management Document.

G.5.3.18 If necessary, additional supplies of gas should be ordered from suppliers or from other healthcare facilities to meet the expected duration of the emergency, following the appropriate procedures specified in the Operational Management Document.

G.5.3.19 Any emergency repairs or actions should be carried out under the control of the AP and controlled by the use of a permit to work.

G.5.3.20 The cause of emergency failure of supply should be investigated immediately and the timescales for the corrective actions specified and where appropriate, corrective actions to rectify the problem initiated immediately.

G.5.3.21 Other areas of the healthcare facility not initially affected might need to be isolated to carry out repairs. In these circumstances, communication and conservation procedures should be instituted in these areas before shutting off the gas supply.

G.5.3.22 Actual emergency situations should be evaluated and appropriate action taken to improve procedures and training to prevent a recurrence.

G.5.4 Permit to work procedure

G.5.4.1 The permit to work procedure should be used to control all planned work on the MGPS. It is used to control the safe withdrawal of the MGPS from service and the manner in which the work is carried out (including the parts of the system affected and the estimated time for completion). It should ensure that the correct procedures and the process for returning the MGPS to service are followed so that the gas supply meets the correct quality specification for patient use.

G.5.4.2 The purpose of the permit issued under the permit to work procedure is to

— safeguard the continuity of supply of gas to the terminal units,

— ensure the safety of the operator working in the vicinity of the MGPS,

— ensure that the MGPS is returned to service in a safe condition, including all examinations where no interruption to the service is anticipated.

Where the work does not involve any planned actions that will affect the supply of medical gases (such as the inspection of terminal units), the MGPS permit to work need not be used.

G.5.4.3 The permit to work procedure is applicable to all preventive maintenance, repairs, alterations or extensions to the existing MGPS, and any action which can affect the supply of the medical gas to the terminal units.

G.5.4.4 The AP should prepare the permit to work prior to commencing the work. Using risk assessment, the AP should identify, from the MGPS drawings, the work to be done, the method statement, all necessary documentation and drawings and the means of isolation.

G.5.4.5 The permit should always be issued to the relevant CPs who are to be engaged in work on the MGPS before any work is started.

G.5.4.6 Work should not be allowed to commence on the MGPS without the permission of the DMO or DNO to allow the designated officers adequate time to make appropriate arrangements to supply medical gases to the patients or equipment, except in an emergency.

G.5.4.7 The permit should remain in force until the work is completed and the MGPS is put back into use, in accordance with the approved procedures. The permit should remain in force for the time defined by the AP on the certificate or earlier if it has been signed off by the CP.

G.5.4.8 If the scope of the work covered by the permit changes, the permit should be cancelled and a new one issued.

G.5.4.9 Procedures using permits for the authorization of work require the fullest cooperation of all staff and their acceptance of the responsibilities involved. The AP should take the lead in coordinating the work and explaining fully the extent and duration of any disruption to the service and ensure that all contractors and nursing staff follow the procedures set out in the permit.

G.5.4.10 The engineering department is responsible for the correct operation of the permit to work procedure. The AP should be responsible for the implementation of the permit to work procedure but might delegate the responsibility of issuing permits to a CP.

G.5.4.11 The AP should use risk management techniques to define the tests to be carried out prior to returning the MGPS back into service. The tests should be detailed on the permit and the test results should be recorded and retained with the permit to work. The AP should authorize the release of the MGPS to allow it to be put back into service.

G.5.4.12 The permit should define the specific test requirements to be carried out prior to returning the MGPS into service and who should be required to witness the tests. The personnel, the measuring instruments used, the components replaced and the problems arising during the activities should be recorded on the permit.

G.5.4.13 The permit should have a unique reference number and be signed and dated by all relevant personnel. The permit to work should be retained in a register for at least five years.

G.5.4.14 The contractor should maintain a register of approved CPs.

G.5.4.15 The AP should use risk management techniques to assess the hazard level for the work to be carried out on the MGPS at the time of preparing the permit and record it on the permit.

G.5.4.16 The AP is responsible for ensuring that the procedures to be used for isolating the MGPS and making it safe to work on are detailed on the permit. The CP is responsible for witnessing the isolation and for making the plant or system safe to be worked on.

G.5.4.17 Once the CP has accepted a permit, he should be responsible for the safe conduct of the work, within the limits of the permit. The work will be subject to the supervision by the AP. The CP should be fully conversant with the terms and requirements of the permit and should give clear instructions to any persons working on the MGPS.

G.5.4.18 Any errors identified in the permits should be corrected and the corrected text initialled by the CP.

G.5.4.19 The CP should sign the permit to certify that work has been completed and request the AP to examine and test the installation.

G.5.4.20 The AP is responsible for ensuring that the work has been satisfactorily completed and should supervise the testing of valve tightness, pressure, cross-connection, flowrate and delivery pressure, and of the alarm system, in accordance with the recommendations on the permit.

G.5.4.21 On satisfactory completion of all tests, the AP should supervise the reconnection of the isolated system to the main system and purging of the MGPS with the specific gas.

G.5.4.22 The AP should inform the DMO or DNO that the work is completed and that the MGPS is now available for use.

G.5.4.23 The AP should remove any "Do Not Use" or other prohibition notices after completion of the work and closing of the permit to work. The AP should retain the completed original permit.

G.5.4.24 Where isolation of the MGPS is required, the preferred method of physical isolation is by means of a break point at the "supply" end of the section of the pipeline to be worked on. This is not required where the work involves only the terminal units. Where physical isolation is not practicable, a risk assessment should be carried out to ensure that the method of isolation provides adequate protection to the system that remains operational.

G.5.5 Change management procedure

G.5.5.1 The change management procedure is a procedure to manage any change process to the MGPS, including alterations and extensions. It also covers related services to ensure that all identified risks and consequences have been addressed to ensure that patient safety and operator safety is not compromised.

G.5.5.2 Any work involving alterations and/or extensions of the MGPS should be subject to the change management procedure, prior to any work being started. This should include a risk assessment to review the implications of the change and the requirement to record any changes to the MGPS, including modifications to the drawings.

Once the alteration has been approved following the change management procedures, the permit to work procedure should be followed to ensure that the MGPS is safely isolated and returned to service.

Table F.1 (*continued*)

Safety objective	Root cause	Hazardous situation	Risk control measures	Responsible organizations
4) **System operation**	a) Incorrect operation or maintenance of the MGPS	Wrong quality of gas/ vacuum supplied to the patient Failure of supply to the patient	Define the correct procedures in the Operational Management Document for each section/component of the MGPS	H+M
			Define responsibilities for all associated staff/users of the MGPS	H
			Define training requirements for all associated staff/users of the MGPS	H
			Ensure that all area shut-off valves, control panels and alarm panels are located in an appropriate location and correctly labelled	H+M
			Train all associated staff/users of the MGPS	H
			Operational Management Document to specify the need to assess competency of all associated staff/users of the MGPS and specify the retraining requirements; recording of training	H
	b) Insufficient resources to operate and manage the MGPS	Wrong quality of gas/ vacuum supplied to the patient Failure of supply to patient or equipment	Review the staffing requirements for safely operating the MGPS (in and out of normal working hours)	H
			Operational Management Document to specify the need to review manning requirements on a regular basis	H
	c) Inappropriate action taken in the event of an emergency condition with the MGPS	Wrong quality of gas/ vacuum supplied to the patient Failure of supply to the patient	Define the correct procedures for the operation of MGPS in an emergency condition	H+M
			Define emergency training requirements for all associated staff/users of the MGPS	H
			Provide emergency training for all associated staff/users of the MGPS	H
			Operational Management Document to specify the need to assess competency of all associated staff/users for emergency operation of the MGPS and to specify the retraining requirements; recording of training	H

Annex G
(informative)

Operational management

G.1 Introduction

The guidance given in this annex represents the best operating management practice for the operation of the MGPS [2] and should be followed, especially where it impacts on patient or staff safety and where extensions, modifications or upgrading of existing installations has occurred.

The primary objective of this annex is to provide guidance for assigning responsibilities to ensure the provision of a safe and reliable MGPS and its efficient operation and use, to maintain patient safety through continuity of supply. This objective will only be achieved if the medical and nursing users and estates staff participate in the introduction of an operational policy designed to minimize the risks resulting from misuse of the system.

This annex looks at issues of operational management including statutory requirements, functional responsibilities, operational procedures, training and communications, cylinders and other sources of supply management, preventive maintenance and repair and risk assessment, giving definitions and working practices throughout.

It is intended for use by operational managers, engineers, quality controllers, technicians, finance officers and other professionals involved in the day-to-day running of an MGPS. One objective of this annex is to clarify the requirements of the operational management system to the healthcare staff and to any contractors involved, prior to its initial use or after any modifications.

The operational management guidance given in this annex should be followed for all installations, including any extensions, modification or upgrading of the MGPS.

The operation of existing installations should be assessed for compliance with this part of ISO 7396, including this annex. A plan for upgrading existing systems should be prepared on the basis of risk management, ensuring that patient safety is maintained throughout the process. Managers will need to liaise with medical colleagues and take account of other published guidance in order to assess the system for technical shortcomings.

G.2 Statutory requirements

G.2.1 It is the responsibility of the owners and occupiers of premises, general managers and chief executives to ensure that their premises and the activities carried out within them comply with all national and regional regulations, which should be listed in the Operational Management Document.

NOTE In Europe, medicinal gases are covered by the following relevant directives:

- EU Directive 2001/83 EC (relating to medicinal products for human use);
- Medical Device Directive 93/42 (concerning the design and construction of medical devices);
- EU Directive 2003/94 EC (detailing the principles and guidelines of good manufacturing practice with regard to medicinal products and investigational medicinal products for human use).

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2) MGPS means Medical Gas Pipeline System.

G.2.2 Medical gases are classified as medicinal products under the pharmaceutical regulations and are, therefore, subject to the same procurement and quality procedures as all other medicinal products. The quality controller (QC) is responsible for quality control of all medicinal products and this includes medical gases, including the manufacture of any medicinal gases on site.

G.3 Functional responsibilities

G.3.1 General

This annex identifies the distinct functions that need to be exercised and the responsibilities that go with them. The titles given here are generic. They describe the individual's role in connection with the MGPS, but are not intended to be prescriptive job titles for terms of employment. Indeed, some of the personnel referred to might not be resident staff but people employed by outside bodies and working on contract.

The following are the key personnel who have specific responsibilities within the operational policy:

a) executive manager (EM);

b) facilities engineering manager (FEM);

c) authorized person (AP);

d) competent person (CP);

e) quality controller (QC);

f) designated medical officer (DMO);

g) designated nursing officer (DNO);

h) designated person (DP).

Some staff can have other responsibilities unconnected with the MGPS and in some cases the same individual can take on more than one role.

In all cases, however, it is essential to identify an AP who is responsible for the day-to-day management of the MGPS and for seeing that the MGPS is operated safely and efficiently and who can decide whether an MGPS should be taken into or out of service.

The EM, FEM and AP can be responsible for more than one MGPS on more than one site.

In order to avoid confusion with other authorized persons, the key personnel mentioned in this annex are always involved with the MGPS.

G.3.2 Executive Manager (EM)

G.3.2.1 The EM is the person with ultimate management responsibility for the organization in which the MGPS is installed and operated, including the allocation of resources and the appointment of personnel.

G.3.2.2 Formal responsibility for the MGPS rests with the EM, although the AP retains effective responsibility for day-to-day management of the MGPS.

G.3.2.3 The EM is responsible for implementation of the operational policy for the MGPS and to ensure that the Operational Management Document clearly defines the roles and responsibilities of all personnel who can be involved in the use, installation, modification and maintenance of the MGPS. The EM is also responsible for monitoring the implementation of the Operational Management Document.

G.3.2.4 The EM might delegate specific responsibilities for the MGPS to key personnel. The extent of the delegation should be clearly set out in the Operational Management Document, together with the arrangements for liaison monitoring and review.

G.3.3 Facilities Engineering Manager (FEM)

G.3.3.1 The FEM is the person with overall responsibility for the MGPS and who needs to have sufficient technical knowledge and experience in order to understand fully the hazards involved during commissioning, construction, operation, maintenance, modification and upgrading of the MGPS. The FEM normally reports to the EM of the healthcare facility.

G.3.3.2 The FEM of the healthcare facility is responsible for the integrity of the MGPS. The FEM might have one or more authorized persons (AP) with clear line management responsibility for the MGPS reporting to him.

G.3.3.3 The FEM is responsible for implementing and monitoring the Operational Management Document covering the MGPS.

G.3.3.4 The FEM is responsible for ensuring that all APs and CPs employed or contracted by the engineering department are competent and qualified.

G.3.3.5 The FEM is responsible for maintaining a registry of competent APs and CPs employed or contracted on site.

G.3.3.6 The FEM is responsible for taking appropriate corrective actions on reported failure or excessive wear of MGPS equipment and components.

G.3.4 Authorized Person (AP)

G.3.4.1 The AP should be appointed in writing by the EM and have sufficient technical knowledge, training and experience to understand fully the hazards involved with the operation of the MGPS. The AP should be appointed in writing by the executive manager or general manager on the recommendation of a chartered engineer with specialist knowledge of MGPSs.

G.3.4.2 The appointed AP is responsible for the day-to-day management of the designated MGPS(s) or section of the MGPS. For a specific MGPS, there can be one or more APs, with clear line management responsibility.

NOTE The Operational Management Document should define the number of APs required to manage the MGPS and the need for an AP to always be available on site or on call.

G.3.4.3 All appointed APs should be listed in the Operational Management Document and be made known to all interested parties on site. The AP should have specific knowledge of the MGPS on site and be independent from the contractor performing the work on the MGPS.

G.3.4.4 The AP is responsible for the following:

a) the issuing of permits and the management and operation of the permit to work procedures related to the MGPS;

b) ensuring that all DNOs in departments likely to be involved are advised of the estimated duration of the work and the interruption to the MGPS;

c) ensuring that all terminal units identified as being faulty or requiring attention are appropriately labelled.

G.3.4.5 The AP should have the responsibility for deciding whether an MGPS should be put into or taken out of service.

Table F.1 (*continued*)

Safety objective	Root cause	Hazardous situation	Risk control measures	Responsible organizations
	f) Poor location or housing of sources of supply	Mechanical damage to the sources of supply leading to loss of supply Sources of supply affected by incident involving an adjacent facility Potential damage to other sources of supply Eventual failure of the supply source Access to all sources of supply blocked, leading to loss of supply	Ensure supply source separation distances follow local regulations /guidelines	H+M
			Review risks associated with two sources of supply being located adjacent to each other	H+M
			Ensure that plant rooms and manifold rooms have adequate temperature control and ventilation Review room temperature control to prevent separation of gas mixtures EXAMPLE To prevent separation of certain gas mixtures, to prevent asphyxiation and to prevent gas accumulation in the room.	H
			Adequate physical protection from mechanical damage	H+M
			Clear signage to keep delivery areas clear	H
			Site procedures to maintain access to sources of supply	H
			Routine review of location of supply system to ensure system remains safe	H
			Review risks associated with having two sources of supply located on different sites	H

Table F.1 *(continued)*

Safety objective	Root cause	Hazardous situation	Risk control measures	Responsible organizations
	g) Failure of alarms	Alarm condition not detected	Uninterrupted Power Supply (UPS) electrical supply to ensure continuity of electrical supply to alarms	M
			Connect alarms to the emergency electrical supply to ensure continuity of alarm operation	H
			Display of information signals independent from alarm system	M
			Routine testing of the alarm system	H
			Routine review of the alarm system	H
			Operational Management Document addresses issues of alarm failure	H
	h) Electricity supply failure	Failure of operation of electrical components potentially leading to loss of supply	Uninterrupted Power Supply (UPS) or emergency electrical supply to ensure continuity of electrical system	H
			Check capacity of the emergency electrical supply	H
			Routine testing of the emergency electrical supply	H
			Operational Management Document addresses issues of electrical supply failure	H
			Procedures to ensure that all components are restored to an operational condition following reinstatement of the power supply	H
			Check that reserve sources of supply from compressors or oxygen concentrators are capable of maintaining gas supply during electrical supply failure.	H
	i) Component failure	Potential for the loss of supply with failure of critical components	Review and identification of critical components	M
			Specific preventive maintenance for critical components	H+M
			Specification for the critical components to be obtained from approved suppliers	M
			Alarm systems checked to ensure that failure of critical components is detected	H
			Adequate spares/redundancy for critical components	H
			Operational Management Document addresses issues of critical component failure	H

Table F.1 (*continued*)

Safety objective	Root cause	Hazardous situation	Risk control measures	Responsible organizations
	j) Failure of the maintenance system	Potential failure of components and subsequent failure of supply system	Operational Management Document addresses issues of critical component failure	H
	k) Supply failure to areas of high-dependency patients	High risk to patient with failure of supply	Identification of areas of high risk	H
			Review of emergency supply systems to high risk areas	H
			Design system to provide higher levels of redundancy of critical components	M
			Alarm systems checked to ensure that failure of critical components is detected	H
			Operational Management Document addresses issues of critical component failure	H
			Capability to supply localized areas	H
2) System performance	a) Incorrect design/ specification of components and pipeline systems	Inadequate supply to the patient or equipment	Provide usage information	H
			Correct design of components/pipelines based on usage information	M
			Design validation in accordance with Clause 12	M
			Commissioning checks following installation	H+M
			Operational Management Document addresses periodic checks of usage	H
	b) Inadequate corrosion protection of pipelines/components	Failure of pipelines/ components Leakages Collapse of supports	Correct design/location/protection of pipelines/components	M
			Operational Management Document addresses periodic inspection and maintenance of MGPS	H

Table F.1 (*continued*)

Safety objective	**Root cause**	**Hazardous situation**	**Risk control measures**	**Responsible organizations**
	c) Failure of pressure control – high pressure	High pressure at the terminal unit	Correct design and location of pressure-relief valves to protect against component failure	M
			Correct design of alarm system to indicate high-pressure condition	M
			Operational Management Document addresses periodic testing and maintenance of pressure-relief valves	H
			Operational Management Document addresses periodic checks of high-pressure alarm	H
			Operational Management Document addresses periodic inspection and maintenance of pressure regulators	H
			Operational Management Document addresses checks of ability of equipment attached to MGPS to cope with failure of pressure control system	H
	d) Failure of pressure control – low pressure	Low pressure at terminal unit leading to malfunctioning of equipment	Correct design of alarm system to indicate low-pressure condition	M
			Operational Management Document addresses periodic checks of low-pressure alarm	H
			Operational Management Document addresses periodic inspection and maintenance of pressure regulators	H

Form D.21.2 — Tests for gas identity using different pressures

Healthcare facility________________ Area identification ________________

COMPLETE INSTALLATION *(Sheet .... of .... sheets)*

This is to certify that the identity of the gas at all terminal units has been checked as follows:

Medical gas	Pressure used	Pressure recorded
Nitrous oxide		
Carbon dioxide		
Nitrogen for driving surgical tools		
Medical air		
Air for driving surgical tools		
Vacuum		

Measuring instrument(s) used ________________

Manufacturer's Representative

Position ________________ Signature ________________

Date ________________ Name ________________

Authorized Person

Position ________________ Signature ________________

Date ________________ Name ________________

Form D.21.3 — Tests for gas identity using a gas-specific analyser

Healthcare facility ______________________ Area identification ______________________

COMPLETE INSTALLATION *(Sheet .... of .... sheets)*

This is to certify that the identity of the gas at all terminal units has been checked as follows:

Medical gas	**Pass/Fail**
Nitrous oxide	
Carbon dioxide	
Nitrogen	

Measuring instrument(s) used ______________________

Manufacturer's Representative

Position ______________________ Signature ______________________

Date ______________________ Name ______________________

Authorized Person

Position ______________________ Signature ______________________

Date ______________________ Name ______________________

Annex E
(informative)

Temperature and pressure relationships

E.1 Principle

From the ideal gas law:

$$\frac{p_2}{T_2} = \frac{p_1}{T_1}$$

and

$$p_2 = (p_1)(T_2/T_1)$$

where

p_1 is the initial pipeline absolute pressure;

p_2 is the final pipeline absolute pressure;

T_1 is the initial pipeline absolute temperature;

T_2 is the final pipeline absolute temperature.

NOTE 1 Absolute pressure = gauge pressure + 100 kPa.

NOTE 2 The relationship between temperature and pressure at typical pipeline pressures is shown in Figure E.1.

E.2 Example

An example of correction using the diagram in Figure E.1 is given below.

The pressure of a system previously at 1 400 kPa will fall to about 1 350 kPa with a 10 °C drop in temperature. This can be confirmed by calculation using the equation in E.1, as follows:

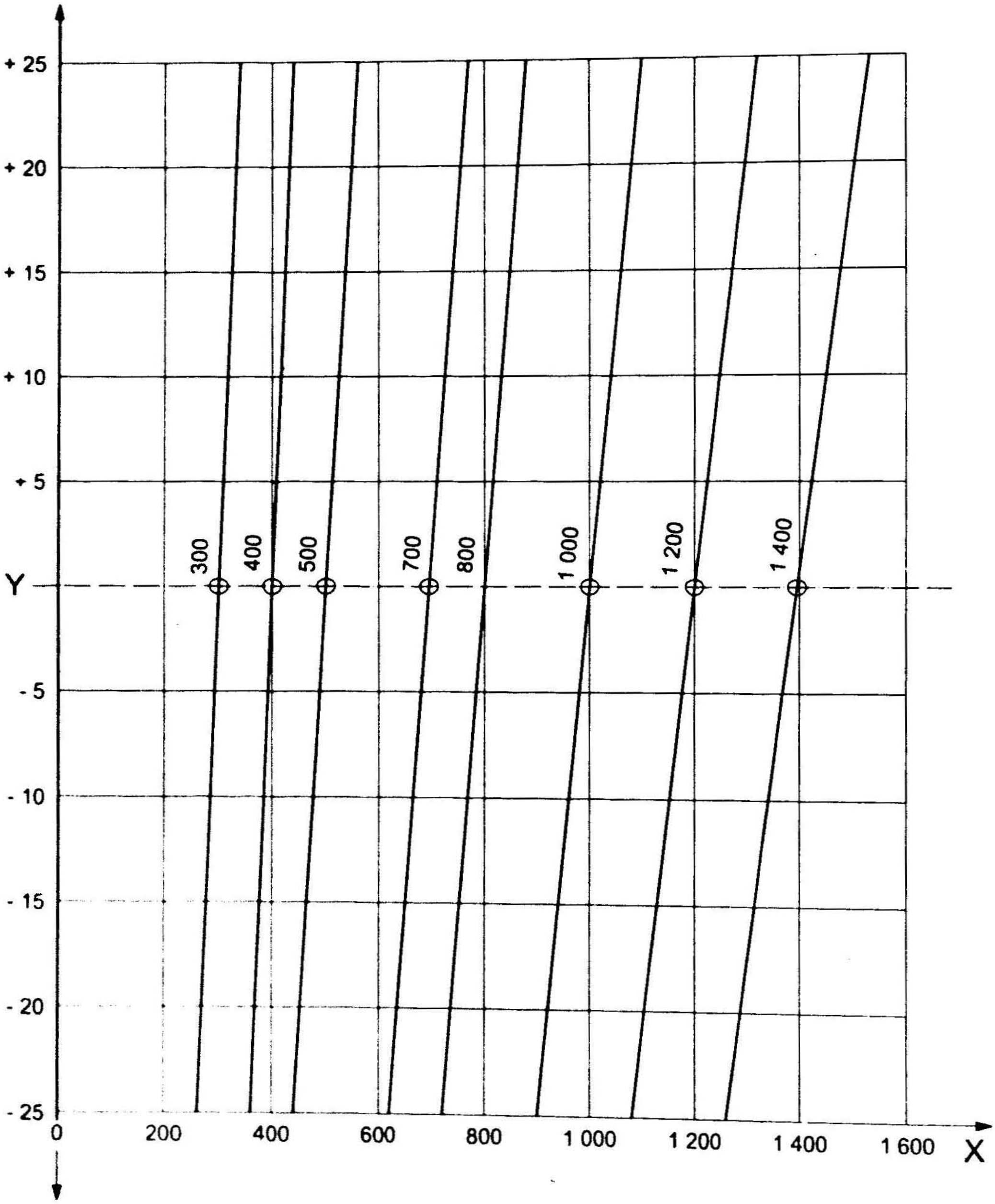
where

p_1 is 1 500 kPa (1 400 kPa gauge pressure);

T_1 is 293 K (20 °C);

T_2 is 283 K (10 °C);

p_2 is 1 449 kPa (1 349 kPa gauge pressure).



Key

X pipeline pressure, in kilopascals (kPa)

Y temperature change, in degrees Celsius (°C)

Figure E.1 — Relationship between temperature and pressure at typical pipeline pressures

Form D.14.2 — Tests of operating alarms

Healthcare facility______________________________ Area identification _________________________

COMPLETE INSTALLATION *(Sheet .... of .... sheets)*

This is to certify that the monitoring and alarm systems have been tested and comply with the specifications

Function tested	Oxygen	Nitrous oxide	Vacuum	Medical air	Air for driving surgical tools	Carbon dioxide	Oxygen-enriched air	Nitrogen for driving surgical tools	Oxygen/ nitrous oxide mixture
Change-over from primary to secondary cylinder supplies									
Primary cylinder supply below minimum pressure or content									
Secondary cylinder supply below minimum pressure or content									
Reserve cylinder supply below minimum pressure or content									
Pressure in cryogenic vessels below minimum									
Liquid level in any cryogenic or non-cryogenic vessel(s) below minimum									
Liquid level in reserve cryogenic or non-cryogenic vessel below minimum									
Malfunctioning of air compressor systems									
Water vapour content in air supplied by air compressor systems									
Malfunctioning of proportioning system									
Malfunctioning of cryogenic systems									
Malfunctioning of vacuum systems									
Malfunctioning of supply system for oxygen-enriched air									

Measuring instrument(s) used ____

Manufacturer's Representative

Position ________________________ Signature ______________________

Date __________________________ Name ________________________

Authorized Person

Position ________________________ Signature ______________________

Date __________________________ Name ________________________

Form D 15 — Test for particulate contamination of pipeline distribution systems

Healthcare facility ____________________ Area identification ____________________

COMPLETE INSTALLATION (*Sheet .... of .... sheets)*

This is to certify that the following medical gas pipelines have been tested for particulate contamination.

Medical gas	Room identification	Terminal unit identification	Visible particles Yes/No

Measuring instrument(s) used ____________________

Manufacturer's Representative

Position ____________________ Signature ____________________

Date ____________________ Name ____________________

Authorized Person

Position ____________________ Signature ____________________

Date ____________________ Name ____________________

Form D 16 — Tests of the quality of medical air produced by supply systems with air compressor(s)

Healthcare facility ______________________ Area identification ______________________

COMPLETE INSTALLATION *(Sheet of sheets)*

This is to certify that the medical air produced by the supply system with air compressor(s) has been tested before filling the pipeline and complies with the requirements of 5.5.2.1 as follows

Oxygen concentration	**Total oil**	**Water vapour content**	**Carbon monoxide**	**Carbon dioxide**	**Sulfur dioxide**	**NO + NO$_2$**	**Particulate contamination**
≥ 20.4 % ≤ 21.4 %	≤ 0.1 mg/m^3	≤ 67 ml/m^3	≤ 5 ml/m^3	≤ 500 ml/m^3	≤ 1 ml/m^3	≤ 2 ml/m^3	

Measuring instrument(s) used ______________________

Manufacturer's Representative

Position ______________________ Signature ______________________

Date ______________________ Name ______________________

Authorized Person

Position ______________________ Signature ______________________

Date ______________________ Name ______________________

Form D.17 — Tests of the quality of air for driving surgical tools produced by supply systems with air compressor(s)

Healthcare facility____________________ Area identification ____________________

COMPLETE INSTALLATION *(Sheet .... of .... sheets)*

This is to certify that the air for driving surgical tools produced by the supply system with air compressor(s) has been tested before filling the pipeline and complies with the requirements of 5.5.2.3 as follows:

Total oil $\leqslant 0{,}1\ \text{mg/m}^3$	**Water vapour content** $\leqslant 67\ \text{ml/m}^3$

Measuring instrument(s) used ____________________

Manufacturer's Representative

Position____________________ Signature____________________

Date ____________________ Name ____________________

Authorized Person

Position____________________ Signature____________________

Date ____________________ Name ____________________

Form D.7 — Tests for leakage, closure, zoning and identification of area shut-off valves

Healthcare facility__________________________ Area identification ________________________

COMPLETE INSTALLATION *(Sheet .... of .... sheets)*

This is to certify that leakage, closure, zoning and identification tests of the terminal units controlled by the area shut-off valves were carried out as follows:

Medical gas	Area shut-off valve identification	Test pressure kPa	Downstream pressure change after 15 min kPa	Identity of terminal units controlled	Correct terminal unit labelling Yes/No	Pass/Fail

Measuring instrument(s) used ____

Manufacturer's Representative

Position ________________________ Signature ________________________

Date ________________________ Name ________________________

Authorized Person

Position ________________________ Signature ________________________

Date ________________________ Name ________________________

Form D.8 — Tests for cross-connections

Healthcare facility________________________ Area identification ________________________

COMPLETE INSTALLATION *(Sheet .... of .... sheets)*

This is to certify that a cross-connection test was successfully completed on the following pipeline systems:

Medical gas	**Section tested**

Measuring instrument(s) used ____________________________________

Manufacturer's Representative

Position________________________ Signature________________________

Date ________________________ Name ________________________

Authorized Person

Position________________________ Signature________________________

Date ________________________ Name ________________________

Form D.9 — Tests for obstruction and flow, mechanical function, gas specificity and identification of terminal units

Healthcare facility________________________ Area identification ______________________

COMPLETE INSTALLATION *(Sheet .... of .... sheets)*

This is to certify that the following terminal units were tested on the .... medical gas pipeline.

Specified flowrate__________ l/min. Specified pressure change _________ kPa.

Room identification	Terminal unit identification	Flowrate Pass/Fail	Pressure change Pass/Fail	Mechanical function Pass/Fail	Identification Pass/Fail	Gas specificity Pass/Fail

Measuring instrument(s) used ______________________________________

Manufacturer's Representative

Position ________________________ Signature ______________________

Date ________________________ Name ______________________

Authorized Person

Position ________________________ Signature ______________________

Date ________________________ Name ______________________

Form D.10 — Tests for obstruction and flow, mechanical function, gas specificity and identification of NIST or DISS connectors

Healthcare facility____________________________ Area identification __________________________

COMPLETE INSTALLATION *(Sheet .... of .... sheets)*

This is to certify that the following NIST or DISS connectors were tested on the .... medical gas pipeline.

Specified flowrate___________ l/min. Specified pressure change___________ kPa.

Room identification	**NIST or DISS connector identification**	**Flowrate** Pass/Fail	**Pressure change** Pass/Fail	**Mechanical function** Pass/Fail	**Identification** Pass/Fail	**Gas specificity** Pass/Fail

Measuring instrument(s) used ____

Manufacturer's Representative

Position____________________________ Signature__________________________

Date ____________________________ Name __________________________

Authorized Person

Position____________________________ Signature__________________________

Date ____________________________ Name __________________________

Form D.3 — Check for compliance with design specifications

Healthcare facility______________________ Area identification ______________________

(Sheet .... of .... sheets)

This is to certify that the following medical gas pipelines have been checked before concealment for compliance with design specifications.

Medical gas	Pipeline sizing	Location of		
		Terminal units	Line pressure regulators (if fitted)	Shut-off valves

Manufacturer's Representative

Position ______________________ Signature ______________________

Date ______________________ Name ______________________

Authorized Person

Position ______________________ Signature ______________________

Date ______________________ Name ______________________

Form D.4.1 — Tests for mechanical integrity of vacuum pipeline systems

Healthcare facility ______________________ Area identification ______________________

(Sheet .... of .... sheets)

This is to certify that a mechanical integrity test was carried out on the vacuum pipeline system(s).

Section tested	**Test pressure** kPa	**Test period** min	**Pass/Fail**

Measuring instrument(s) used ______________________

Manufacturer's Representative

Position ______________________ Signature ______________________

Date ______________________ Name ______________________

Authorized Person

Position ______________________ Signature ______________________

Date ______________________ Name ______________________

Form D.4.2 — Tests for leakage into the vacuum pipeline systems

Healthcare facility____________________________ Area identification ____________________________

(Sheet .... of .... sheets)

This is to certify that a leakage test was carried out on the vacuum pipeline system(s). During the test, the pressures shown below were measured.

Section tested	**Test pressure** kPa	**Test period** h	**Pressure increase** Δp kPa	· **Pass/Fail** $\Delta p \leq 20$ kPa/h

Measuring instrument(s) used ____

Manufacturer's Representative

Position ____________________________ Signature ____________________________

Date ____________________________ Name ____________________________

Authorized Person

Position ____________________________ Signature ____________________________

Date ____________________________ Name ____________________________

Form D.5.1 — Tests for mechanical integrity for compressed medical gas pipeline systems

Healthcare facility________________________ Area identification ________________________

(Sheet .... of .... sheets)

This is to certify that a mechanical integrity test was carried out before concealment on the medical gas pipeline system(s).

Medical gas	**Section tested**	**Test pressure** kPa	**Test period** min	**Pass/Fail**

Measuring instrument(s) used ____

Manufacturer's Representative

Position________________________ Signature________________________

Date ________________________ Name ________________________

Authorized Person

Position________________________ Signature________________________

Date ________________________ Name ________________________

C.3.11.2 Example of procedure

Test the terminal unit most distant from the source of supply on each branch line of the pipeline with the device shown in Figure : at a flowrate of 150 l/min for 15 s. Verify that the filters are free from particulate matter when viewed in good light.

C.3.11.3 Test results

Record the results on Form D.15.

C.3.12 Tests of quality of medical air and air for driving surgical tools produced by supply systems with air compressor(s) (see 12.6.11 and 12.6.12)

C.3.12.1 General

These tests should be carried out on each air compressor unit in turn, at the sample port immediately downstream of the conditioning systems, before filling the pipeline distribution system with air from the compressor system. The supply system should be isolated from the pipeline distribution system by closing the supply shut-off valve.

NOTE Information regarding test methods can be found in ISO 8573-3 [8], ISO 8573-4 [9], ISO 8573-6 [11] and ISO 8573-8 [12].

C.3.12.2 Example of procedure

C.3.12.2.1 Oxygen concentration

Using an oxygen analyser, verify that the oxygen concentration meets the requirements of 5.5.2.1.

C.3.12.2.2 Oil

Test for oil present as liquid, aerosol and vapour at the sample port using an appropriate test device. Verify that the total oil concentration does not exceed the value given in 5.5.2.1 and 5.5.2.3.

NOTE Information regarding test methods can be found in ISO 8573-2 [7] and ISO 8573-5 [10].

C.3.12.2.3 Water

Test for water vapour content at the sample port using an appropriate test device. Verify that the water vapour content does not exceed the value given in 5.5.2.1 or 5.5.2.3. This test should be repeated after filling the pipeline distribution system with air from a sample of 5 % of terminal units at points remote from the source of supply (see C.3.15.2.5).

C.3.12.2.4 Carbon monoxide and carbon dioxide

Determine the concentrations of carbon monoxide and carbon dioxide at the sample port using appropriate test devices. Verify that the concentrations do not exceed the values given in 5.5.2.1.

NOTE Information regarding test methods can be found in ISO 8573-6 [11].

C.3.12.2.5 Sulfur dioxide, nitrogen monoxide and nitrogen dioxide

Determine the concentrations of sulfur dioxide, nitrogen monoxide and nitrogen dioxide at the sample port using appropriate test devices. Verify that the concentrations do not exceed the values given in 5.5.2.1.

C.3.12.2.6 Particulate contamination

Test for particulate contamination at the sample port using an appropriate test device.

C.3.12.3 Test results

For medical air, record the results on Form D.16. For air for driving surgical tools, record the results on Form D.17.

C.3.13 Test of the quality of medical air produced by supply systems with proportioning unit(s) (see 12.6.13)

C.3.13.1 General

These tests should be carried out before filling the pipeline distribution system with medical air produced by the proportioning system. The supply system should be isolated from the pipeline distribution system by closing the supply shut-off valve.

These tests should be carried out on each proportioning system in turn, if more than one is fitted, at a suitable sample port on each system immediately upstream of the supply shut-off valve.

C.3.13.2 Example of procedure

C.3.13.2.1 Oxygen concentration

Using an oxygen analyser, verify that the oxygen concentration meets the requirements of 5.5.3.1.

C.3.13.2.2 Water vapour content

Using an appropriate test device at the sample port, verify that the water vapour content does not exceed the value given in 5.5.3.1.

C.3.13.3 Test results

Record the results on Form D.18.

C.3.14 Test of the quality of oxygen-enriched air produced by supply systems with oxygen concentrator(s) (see 12.6.14)

C.3.14.1 General

These tests should be carried out before filling the pipeline distribution system with oxygen-enriched air. The supply system should be isolated from the pipeline distribution system by closing the supply shut-off valve.

These tests should be carried out on each oxygen concentrator in turn at a suitable test point immediately upstream of the supply shut-off valve.

C.3.14.2 Example of procedure

C.3.14.2.1 Oxygen concentration

Using an oxygen analyser, verify that the oxygen concentration meets the requirements of ISO 10083.

C.3.14.2.2 Carbon monoxide and carbon dioxide

Using appropriate test devices at the sample port, verify that the concentrations of carbon monoxide and carbon dioxide do not exceed the levels specified in ISO 10083

C.3.14.2.3 Particulate contamination

Using appropriate test devices at the sample port, verify that the particulate contamination does not exceed the level specified in ISO 10083.

C.3.14.2.4 Hydrocarbon contamination

Using appropriate test devices at the sample port, verify that the concentration of hydrocarbons does not exceed the level specified in ISO 10083

C.3.14.2.5 Water vapour content

Using appropriate test devices at the sample port, verify that the water vapour content does not exceed the level specified in ISO 10083.

C.3.14.3 Test results

Record the results on Form D 19.

C.3.15 Filling with specific gas (see 12.6.15)

C.3.15.1 General

All systems can be filled with their specific gases at the same time Filling with specific gas can be carried out at the same time as the test for gas identity (see C.3.16). All previous tests should have been satisfactorily completed. Sources of test gas should be disconnected All pipeline systems should be at atmospheric pressure. Each pipeline system should be connected to its source of supply with all shut-off valves except the supply shut-off valve open. All special connectors should be removed from site

C.3.15.2 Example of procedure

C.3.15.2.1 Open the supply shut-off valve and fill each pipeline system from its supply system to the nominal distribution pressure or vacuum.

C.3.15.2.2 Except for vacuum pipelines, allow a flow of gas from each terminal unit in turn Close the supply shut-off valve and allow the pressure in each pipeline to fall to atmospheric All gases except air should be vented outside the building.

C.3.15.2.3 Open the supply shut-off valve and refill each pipeline to the nominal distribution pressure. Repeat the procedure given in C.3.15.2.1 and C.3.15.2.2 as many times as required to give a gas identity which conforms to the requirements of 12.6.15

C.3.15.2.4 Leave each pipeline system at nominal distribution pressure with the supply system connected

C.3.15.2.5 For medical air or air for driving surgical tools supplied by supply systems with air compressors, at least one terminal unit on each branch (the terminal unit most distant from the source of supply) should be tested for water vapour content.

C.3.15.3 Test results

Record on Form D.20 that all pipeline systems are filled with the specific gas

C.3.16 Tests for gas identity (see 12.6.16)

C.3.16.1 General

The pipeline systems should be at nominal distribution pressure and filled with the specific gases. All pipeline systems should be tested at the same time. No medical equipment should be connected to the pipeline systems. All other tests in C.3 should have been satisfactorily completed before this test is carried out.

C.3.16.2 Example of procedure

Test all terminal units as follows:

a) for each pipeline system which contains gas with a characteristic oxygen concentration [e.g. oxygen (100 % volume fraction), oxygen-enriched air (in accordance with specification), oxygen/nitrous oxide mixture (in accordance with specification), medical air (21 % volume fraction) and air for driving surgical tools (21 % volume fraction)], measure the oxygen concentration using an oxygen analyser. For pipeline systems which contain gas with the same characteristic oxygen concentration but at different pressures (e.g. medical air, 400 kPa and air for driving surgical tools, 800 kPa), measure the pressure using a pressure gauge;

b) for each pipeline system which does not contain oxygen (except as a contaminant), either use a gas-specific analyser or set each system to a different pressure and measure the static pressure. After such a procedure, the pressure should be reset to the nominal distribution pressure for each system;

c) for vacuum systems, measure the pressure using a vacuum gauge.

C.3.16.3 Test results

Record the results on Form D.21.1 and/or Form D.21.2 and/or Form D.21.3.

Annex C
(informative)

Example of procedure for testing and commissioning

C.1 General

This test procedure is given as an example of how the specifications of Clause 12 can be verified so that the system can be commissioned and certified. Other procedures which validly test these specifications can be devised. In this procedure, the given sequence of tests is important and should be followed. The general requirements of 12.1 and 12.2 should be followed. When the results of a test do not meet the pass criteria, remedial work shall be carried out and previous tests repeated as necessary.

The accuracy of the test equipment should be checked before commencing each test procedure.

Typical forms for certification of the system are given in Annex D. Summaries of the typical tests required which list the specification, procedure and form for each test are given in Forms D.1.1 and D.1.2.

C.2 Inspections before concealment (see 12.3)

C.2.1 Inspection of marking and pipeline supports (see 12.5.1)

C.2.1.1 General

Visually inspect that marking has been correctly placed on all pipelines, especially adjacent to T-connections and where pipelines pass through floors or wall partitions. The marking should be in accordance with 10.1. Check the pipeline supports. The pipeline supports should be in accordance with 11.2.

C.2.1.2 Test results

Record the results on Form D.2.

C.2.2 Check for compliance with the design specifications (see 12.5.2)

C.2.2.1 General conditions

No pipeline should be concealed.

C.2.2.2 Example of procedure

Visually inspect each pipeline to check that the sizing of the pipelines, the location of terminal units, line pressure regulators (if fitted) and shut-off valves are in accordance with the design specification.

C.2.2.3 Test results

Record the results on Form D.3.

C.3 Tests and procedures before use of the systems (see 12.4)

C.3.1 Tests for leakage and mechanical integrity

C.3.1.1 Tests for mechanical integrity of vacuum pipeline systems (see 12.6.1.1)

WARNING — Precautions should be taken to avoid hazards to personnel arising from possible rupture of the pipeline.

C.3.1.1.1 General

This test can be carried out on sections of the pipeline, provided that no part of the system is omitted. The section to be tested should be completely installed and held firmly in place. The base blocks of all terminal units should be fitted and blanked. All connectors for pressure-relief valves, pressure gauges and pressure switches should be blanked. If separate sections are tested, each section under test should be isolated from the remainder of the system.

C.3.1.1.2 Example of procedure

Connect a suitable pressure-measuring device to the section under test. Fill the section(s) to be tested with test gas at 500 kPa. After 5 min, check that the system has not ruptured.

C.3.1.1.3 Test results

Record the results on Form D.4.1

C.3.1.2 Test for leakage into the vacuum pipeline system (see 12.6.1.2)

C.3.1.2.1 General

All terminal units, valves and other devices such as vacuum gauges and pressure switches should have been installed. The vacuum supply system should be connected to the system under test.

C.3.1.2.2 Example of procedure

Connect a vacuum gauge to the system. Operate the vacuum supply system until the nominal distribution pressure is achieved. With the system at nominal distribution pressure, isolate the vacuum supply system. Check that the pressure increase after 1 h does not exceed 20 kPa with all shut-off valves open.

C.3.1.2.3 Test results

Record the results on Form D.4.2.

C.3.1.3 Test for mechanical integrity for compressed medical gas pipeline systems (see 12.6.1.3)

WARNING — Precautions should be taken to avoid hazards to personnel arising from possible rupture of the pipeline.

C.3.1.3.1 General

This test can be carried out on sections of the pipeline, provided that no part of the system is omitted. The section to be tested should be completely installed and held firmly in place. The base blocks of all terminal units should be fitted and blanked. All connectors for pressure-relief valves, pressure gauges and pressure switches should be blanked. If separate sections are tested, each section under test should be isolated from the remainder of the system.

C.3.1.3.2 Example of procedure

Connect a suitable pressure-measuring device to the section under test. Fill the section(s) to be tested with test gas at a pressure 1,2 times the maximum pressure as specified in 12.6.1.3 for that section. After 5 min, check that the system has not ruptured.

C.3.1.3.3 Test results

Record the results on Form D.5.1.

C.3.1.4 Test for leakage from the compressed medical gas pipeline systems (see 12.6.1.4)

C.3.1.4.1 General

These tests can be carried out on sections of each pipeline, provided that no section is omitted and the integrity of the pipeline is maintained. All terminal units, valves, line pressure regulators, gauges and pressure sensors should be fitted. The supply system should be isolated from the pipeline.

C.3.1.4.2 Example of procedure

Connect a suitable pressure-measuring device to each section of the system(s) under test.

For single-stage pipeline distribution systems, pressurize with test gas at nominal distribution pressure each section upstream and downstream of each area shut-off valve. The means to allow physical isolation shall be used between each section upstream and downstream of each area shut-off valve.

For double-stage pipeline distribution systems, pressurize with test gas at nominal supply system pressure each section upstream of each line pressure regulator and at nominal distribution pressure each section downstream of each area line pressure regulator. The means to allow physical isolation shall be used between sections upstream and downstream of each line pressure regulator.

NOTE The shut-off valves fitted upstream and downstream of each line pressure regulator (see 7.4.2) together with the line pressure regulator set at zero flow can be considered as a means to allow physical isolation.

Disconnect and remove the test gas supply. Record the pressure and room temperature initially and at the end of the test period (2 h to 24 h). Check that in each section upstream of each area shut-off valve (or each line pressure regulator), the pressure drop does not exceed 0,025 % of the initial test pressure per hour. Check that in each section downstream of each area shut-off valve (or line pressure regulator), the pressure drop does not exceed 0,4 %/h of the initial test pressure in sections not including flexible hoses in medical supply units or 0,6 %/h of the initial test pressure in sections including flexible hoses in medical supply units.

C.3.1.4.3 Test results

Record the results on Forms D.5.2 and D.5.3.

C.3.1.5 Combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems (before concealment) (see 12.6.1.5)

WARNING — Precautions should be taken to avoid hazards to personnel arising from possible rupture of the pipeline.

C.3.1.5.1 General

This test can be carried out on sections of the pipeline, provided that no part of the system is omitted. The supply system should be isolated from the pipeline. The section to be tested should be completely installed and held firmly in place. The base blocks of all terminal units should be fitted and blanked. All connectors for pressure-relief valves, pressure gauges and pressure switches should be blanked. If separate sections are tested, each section under test should be isolated from the remainder of the system.

C.3.1.5.2 Example of procedure

C.3.1.5.2.1 Connect a suitable pressure-measuring device to the section under test. Pressurize with test gas each section to be tested at a pressure 1,2 times the maximum pressure, as specified in 12.6.1.5, for that section. After 5 min, check that the system has not ruptured.

C.3.1.5.2.2 At the same test pressure(s), check that the pressure drop during a test period of 2 h to 24 h does not exceed 0,025 % of the initial test pressure per hour, except for pressure changes due to temperature variations.

NOTE The pressure change due to temperature variations is approximately 0,35 %/°C (see Annex E).

C.3.1.5.3 Test results

Record the results on Form D.6.1.

C.3.1.6 Combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems (after concealment) (see 12.6.1.6)

WARNING — Precautions should be taken to avoid hazards to personnel arising from possible rupture of the pipeline.

C.3.1.6.1 General

These tests may be carried out on sections of each pipeline provided that no section is omitted and the integrity of the pipeline is maintained. All terminal units, valves, line pressure regulators, gauges and pressure sensors should be fitted. The supply system should be isolated from the pipeline.

C.3.1.6.2 Example of procedure

C.3.1.6.2.1 Connect a suitable pressure-measuring device to the section under test. Pressurize with test gas each section to be tested at a pressure 1,2 times the maximum pressure, as specified in 12.6.1.6, for that section. After 5 min, check that the system has not ruptured.

C.3.1.6.2.2 Carry out the test for leakage in accordance with 12.6.1.4.

C.3.1.6.3 Test results

Record the results on Form D.6.2, Form D.5.2 and/or Form D.5.3.

C.3.2 Test of area shut-off valves for leakage and closure and checks for correct zoning and correct identification (see 12.6.2)

C.3.2.1 General

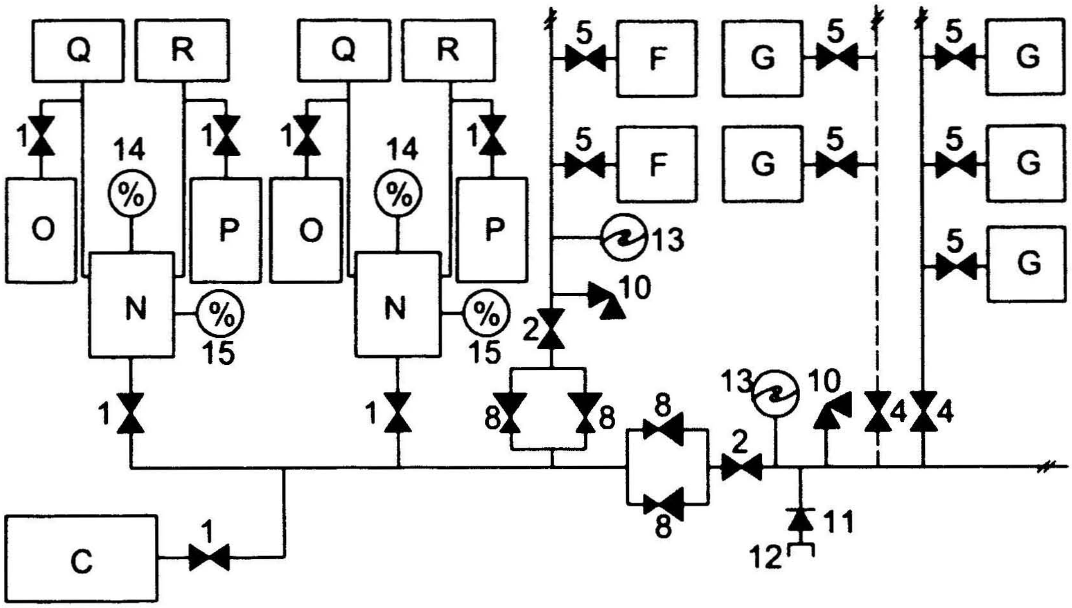
The tests given in C.3.1 should have been completed satisfactorily and all terminal units should be closed.

This test can be carried out on more than one system at a time.

The test for leakage and closure of area shut-off valves does not apply to vacuum systems.

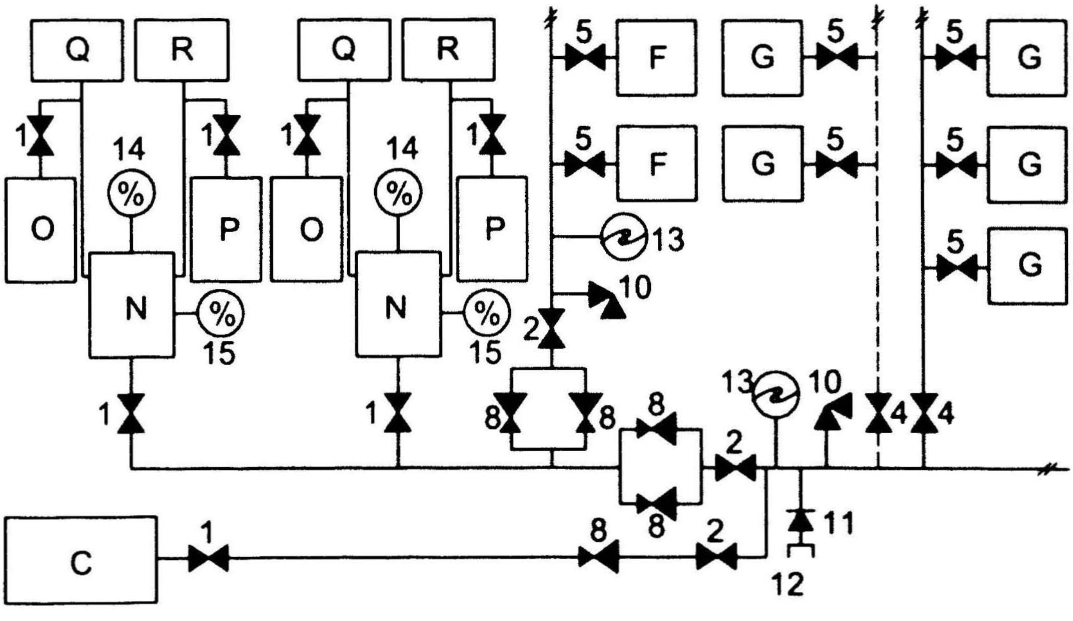
C.3.2.2 Example of procedure

C.3.2.2.1 Pressurize the pipeline system at its nominal distribution pressure with all area shut-off valves open. Connect a pressure-measuring device downstream of each area shut-off valve. Close all area shut-off valves.



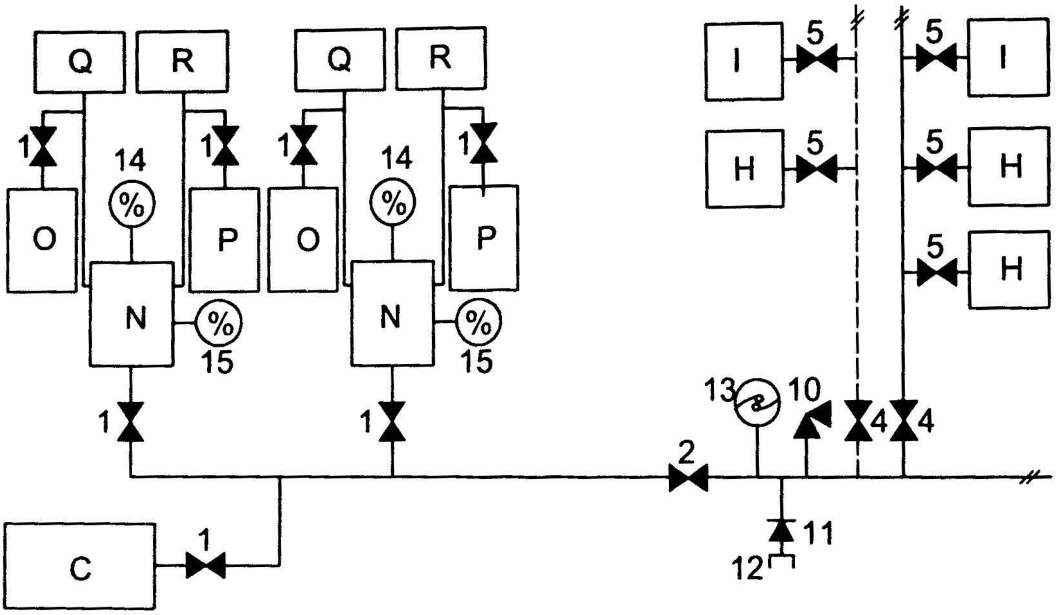
NOTE See Tables A.2 and A.3 for keys to components and subassemblies

Figure A.19 — Single-stage pipeline system with proportioning supply system (two proportioning units – one cylinder source)



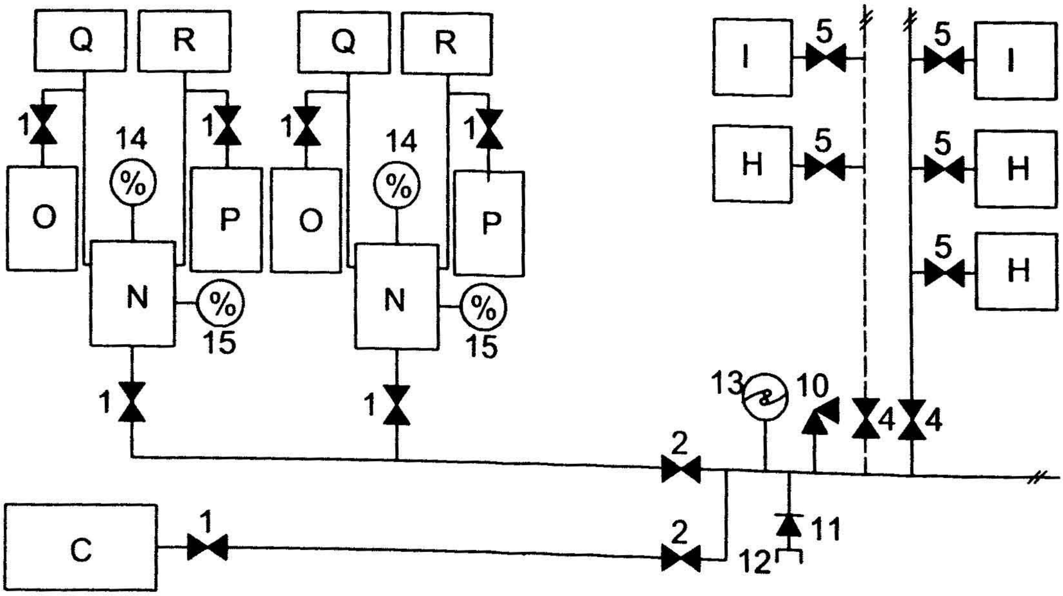
NOTE See Tables A.2 and A.3 for keys to components and subassemblies

Figure A.20 — Single-stage pipeline system with proportioning supply system (two proportioning units – one cylinder source) — Alternative arrangement of secondary and reserve supply connection



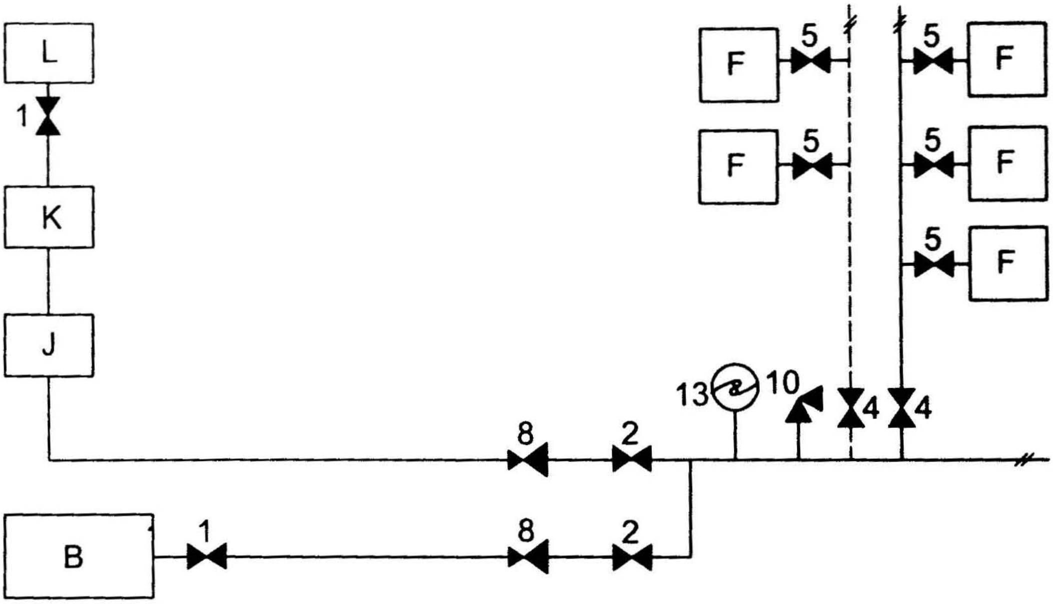
NOTE See Tables A.2 and A.3 for keys to components and subassemblies.

Figure A.21 — Double-stage pipeline system with proportioning supply system (two proportioning units – one cylinder source)



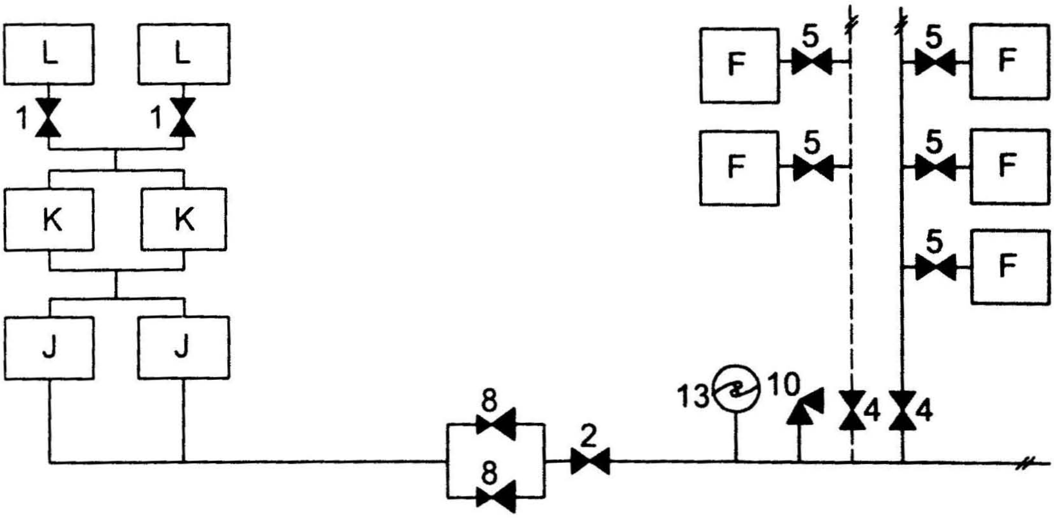
NOTE See Tables A.2 and A.3 for keys to components and subassemblies.

Figure A.22 — Double-stage pipeline system with proportioning supply system (two proportioning units – one cylinder source) — Alternative arrangement of secondary and reserve supply connection



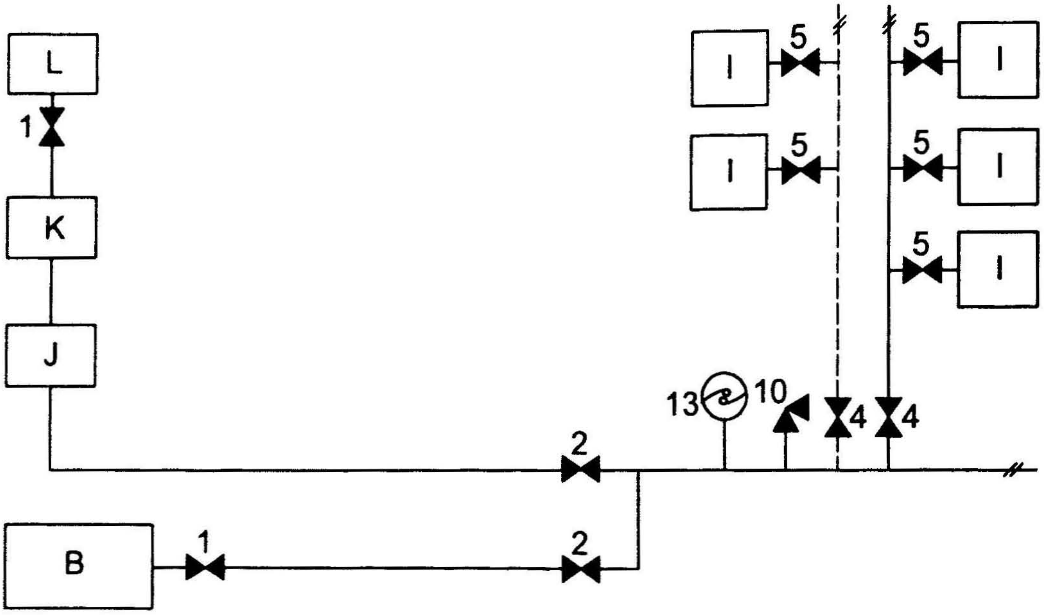
NOTE See Tables A.2 and A.3 for keys to components and subassemblies.

Figure A.23 — Single-stage pipeline system with compressor supply system for air for driving surgical tools (one air compressor source – one cylinder source)



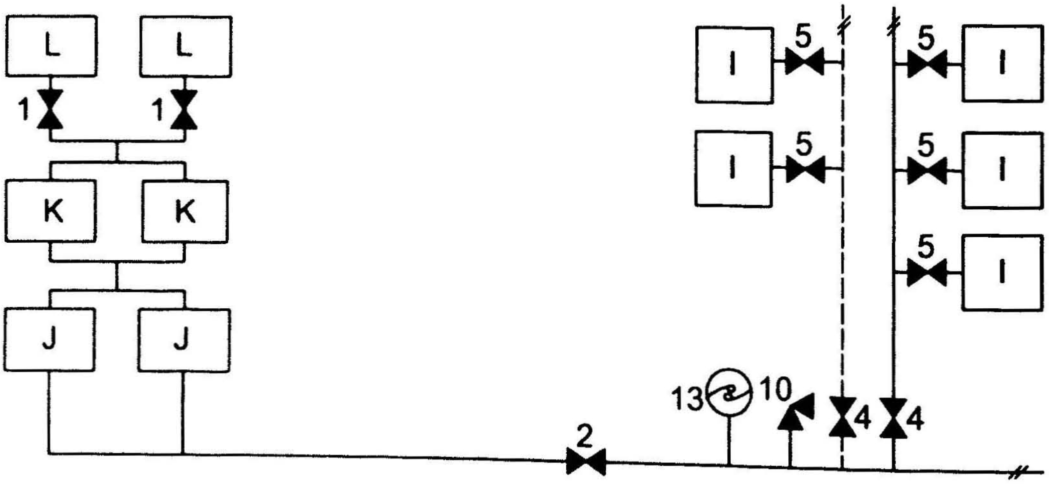
NOTE See Tables A.2 and A.3 for keys to components and subassemblies.

Figure A.24 — Single-stage pipeline system with compressor supply system for air for driving surgical tools (two air compressor sources)



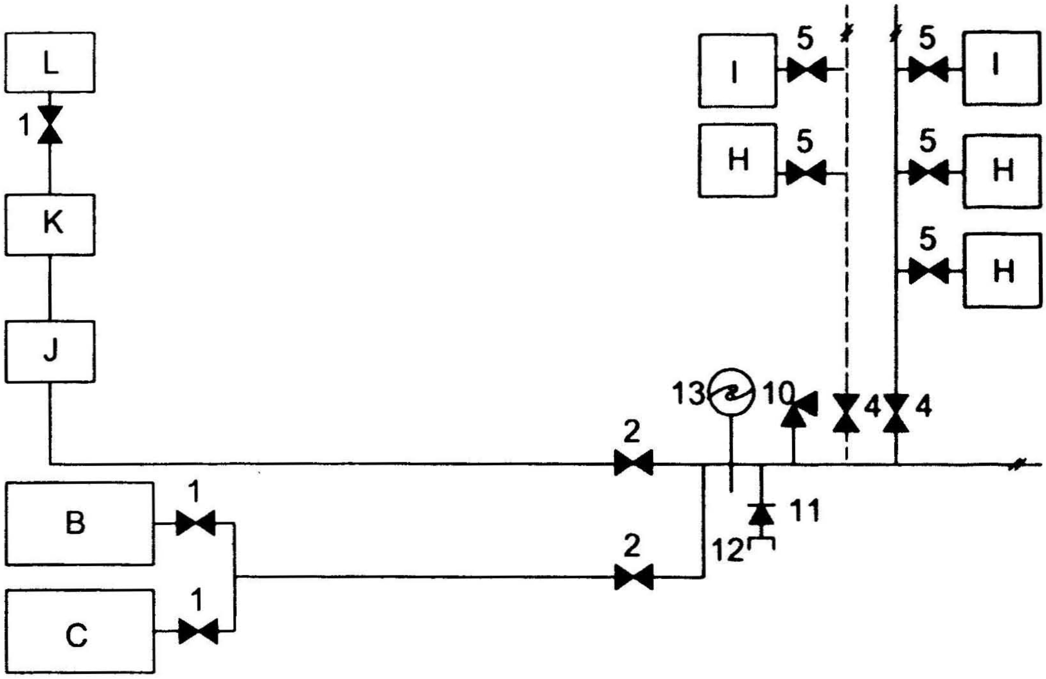
NOTE See Tables A.2 and A.3 for keys to components and subassemblies.

Figure A.25 — Double-stage pipeline system with compressor supply system for air for driving surgical tools (one air compressor source – one cylinder source)



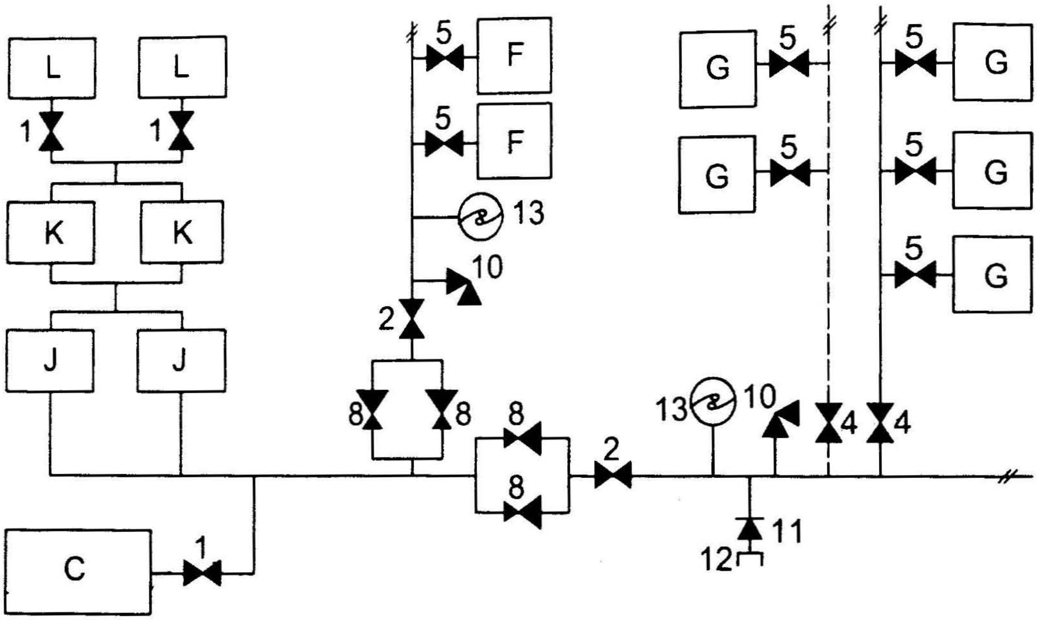
NOTE See Tables A.2 and A.3 for keys to components and subassemblies.

Figure A.26 — Double-stage pipeline system with compressor supply system for air for driving surgical tools (two air compressor sources)



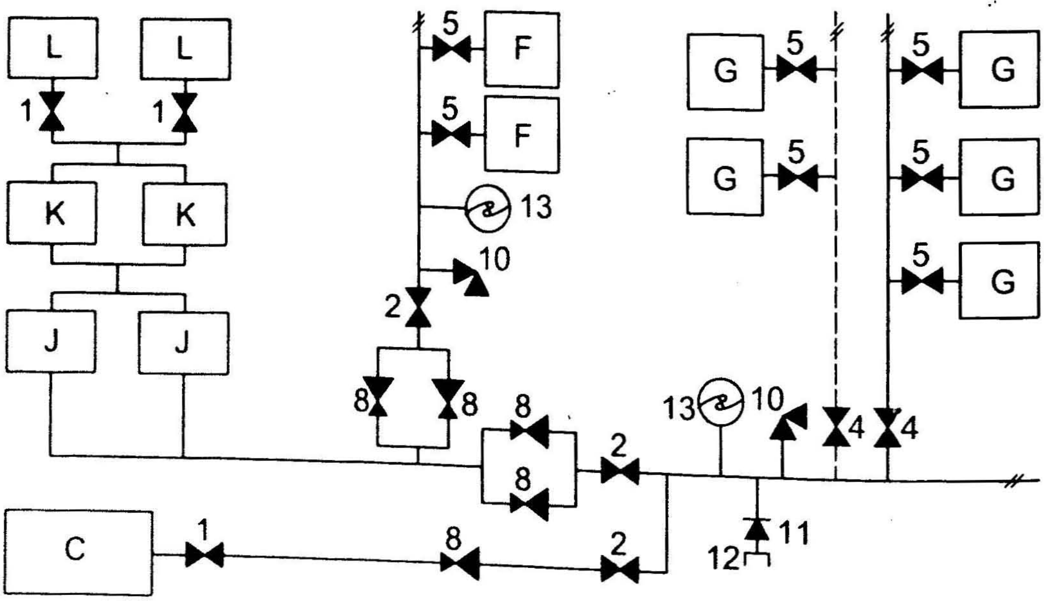
NOTE See Tables A 2 and A.3 for keys to components and subassemblies

Figure A.7 — Double-stage pipeline system with air compressor supply system (one air compressor source – two cylinder sources) — Alternative arrangement of secondary and reserve supply connection



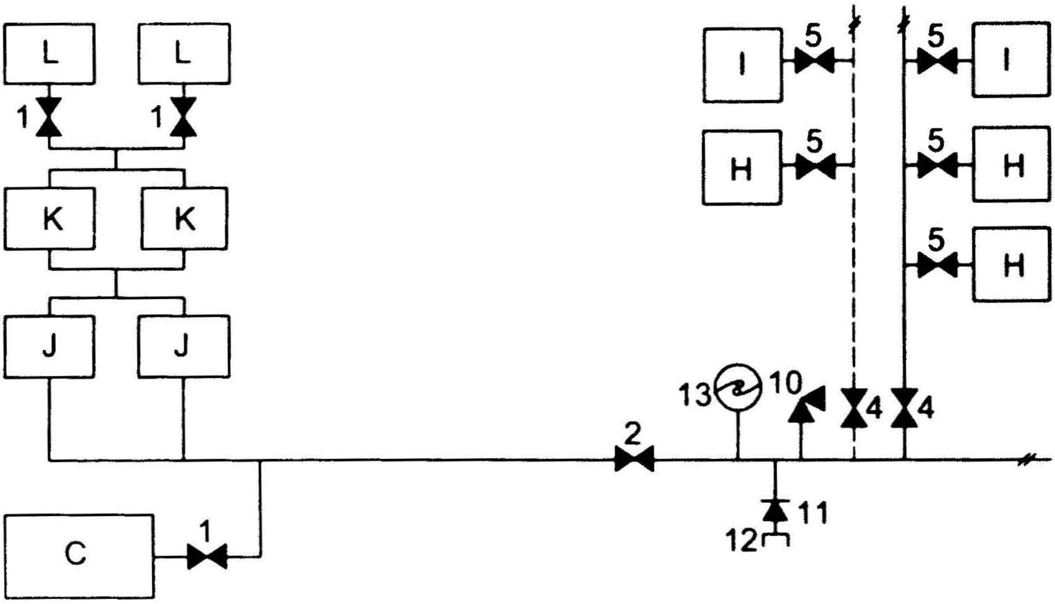
NOTE See Tables A.2 and A.3 for keys to components and subassemblies.

Figure A.8 — Single-stage pipeline system with air compressor supply system (two air compressor sources – one cylinder source)



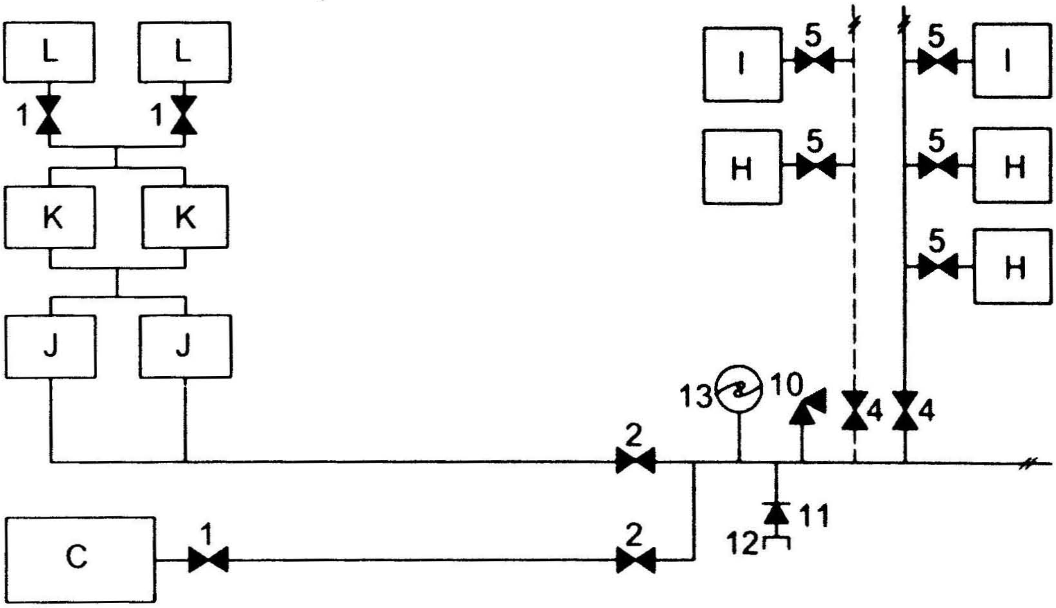
NOTE See Tables A.2 and A.3 for keys to components and subassemblies.

Figure A.9 — Single-stage pipeline system with air compressor supply system (two air compressor sources – one cylinder source) — Alternative arrangement of reserve supply connection



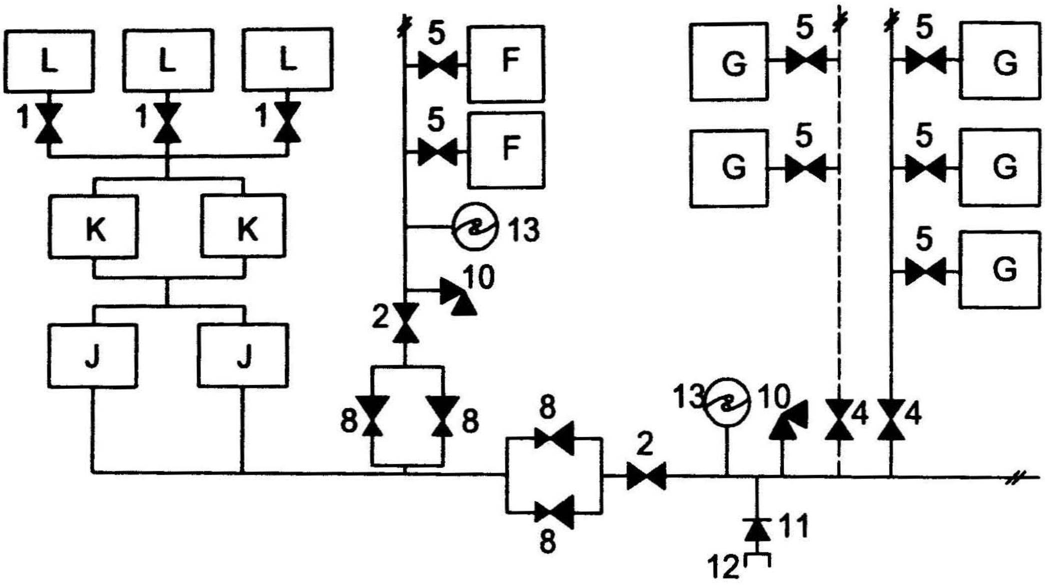
NOTE See Tables A 2 and A 3 for keys to components and subassemblies

Figure A.10 — Double-stage pipeline system with air compressor supply system (two air compressor sources – one cylinder source)



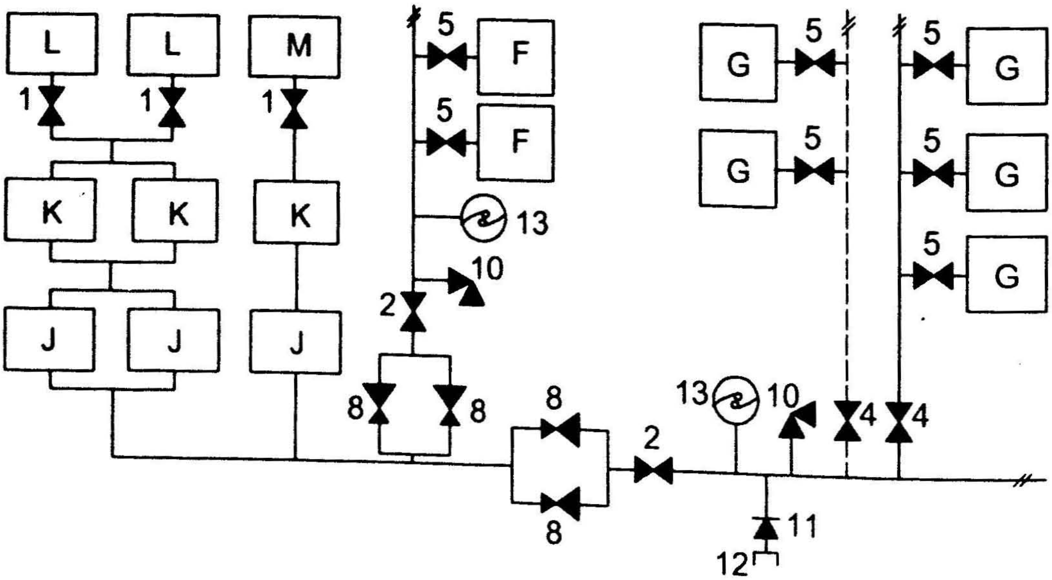
NOTE See Tables A 2 and A 3 for keys to components and subassemblies

Figure A.11 — Double-stage pipeline system with air compressor supply system (two air compressor sources – one cylinder source) — Alternative arrangement of reserve supply connection



NOTE See Tables A.2 and A.3 for keys to components and subassemblies.

Figure A.12 — Single-stage pipeline system with air compressor supply system (three air compressor sources)



NOTE See Tables A.2 and A.3 for keys to components and subassemblies.

Figure A.13 — Single-stage pipeline system with air compressor supply system (three air compressor sources) — Alternative arrangement of reserve air compressor supply connection

Annex A
(informative)

Schematic representations of typical supply systems and area distribution systems

These schematic representations are intended to give an overview of the essential features of different types of medical gas pipeline systems. The relative position of some components shown can be varied to meet local needs. Many components defined in the requirements of this part of ISO 7396 are not shown (e.g. automatic change-over). Dashed lines indicate additional pipelines. These schematics are for general guidance and are not normative.

Table A.1 gives a summary of Figures A.1 to A.30. Tables A.2 and A.3 give the keys to the components and subassemblies, respectively, of the features shown in Figures A.1 to A.30.

Table A.1 — Description of the figures

Figure number	Description
A.1	Single-stage pipeline system (three sources of supply)
A.2	Single-stage pipeline system (three sources of supply) — Alternative arrangement of reserve supply connection
A.3	Double-stage pipeline system (three sources of supply)
A.4	Double-stage pipeline system (three sources of supply) — Alternative arrangement of reserve supply connection
A.5	Single-stage pipeline system with air compressor supply system (one air compressor source - two cylinder sources)
A.6	Double-stage pipeline system with air compressor supply system (one air compressor source - two cylinder sources)
A.7	Double-stage pipeline system with air compressor supply system (one air compressor source - two cylinder sources) — Alternative arrangement of secondary and reserve supply connection
A.8	Single-stage pipeline system with air compressor supply system (two air compressor sources - one cylinder source)
A.9	Single-stage pipeline system with air compressor supply system (two air compressor sources - one cylinder source) — Alternative arrangement of reserve supply connection
A.10	Double-stage pipeline system with air compressor supply system (two air compressor sources - one cylinder source)
A.11	Double-stage pipeline system with air compressor supply system (two air compressor sources - one cylinder source) — Alternative arrangement of reserve supply connection
A.12	Single-stage pipeline system with air compressor supply system (three air compressor sources)
A.13	Single-stage pipeline system with air compressor supply system (three air compressor sources) — Alternative arrangement of reserve air compressor supply connection
A.14	Double-stage pipeline system with air compressor supply system (three air compressor sources)
A.15	Double-stage pipeline system with air compressor supply system (three air compressor sources) — Alternative arrangement of reserve air compressor supply connection
A.16	Single-stage pipeline system with proportioning supply system (one proportioning unit - two cylinder sources)

Table A.1 (*continued*)

Figure number	Description
A.17	Double-stage pipeline system with proportioning supply system (one proportioning unit – two cylinder sources)
A.18	Double-stage pipeline system with proportioning supply system (one proportioning unit – two cylinder sources) — Alternative arrangement of secondary and reserve supply connection
A.19	Single-stage pipeline system with proportioning supply system (two proportioning units – one cylinder source)
A.20	Single-stage pipeline system with proportioning supply system (two proportioning units – one cylinder source) — Alternative arrangement of secondary and reserve supply connection
A.21	Double-stage pipeline system with proportioning supply system (two proportioning units – one cylinder source)
A.22	Double-stage pipeline system with proportioning supply system (two proportioning units – one cylinder source) — Alternative arrangement of secondary and reserve supply connection
A.23	Single-stage pipeline system with compressor supply system for air for driving surgical tools (one air compressor source – one cylinder source)
A.24	Single-stage pipeline system with compressor supply system for air for driving surgical tools (two air compressor sources)
A.25	Double-stage pipeline system with compressor supply system for air for driving surgical tools (one air compressor source – one cylinder source)
A.26	Double-stage pipeline system with compressor supply system for air for driving surgical tools (two air compressor sources)
A.27	Vacuum pipeline system (three vacuum sources)
A.28	Area distribution system for single-stage pipeline distribution system (with no additional pressure regulators)
A.29	Area distribution system for double-stage pipeline distribution system with two parallel line pressure regulators
A.30	Area distribution system for double-stage pipeline distribution system — Additional cylinder with pressure regulator permanently connected to pipeline

Table A.2 — Key to components in Figures A.1 to A.30

Number	Component
1	Source shut-off valve
2	Main shut-off valve
3	Connector to pipeline
4	Riser shut-off valve
5	Branch shut-off valve
6	Area shut-off valve
7	Maintenance shut-off valve
8	Line pressure regulator
9	Terminal unit
10	Pressure-relief valve
11	Non-return valve
12	Maintenance supply assembly
13	Pressure alarm switch
14	Oxygen analyser 1
15	Oxygen analyser 2
16	Flexible connector
17	Cylinder with cylinder valve
18	Cylinder pressure regulator (supplying nominal pipeline distribution pressure)

Table A.3 — Key to subassemblies in Figures A.1 to A.30

Letter	Subassembly
A	Primary source of supply with a manifold pressure regulator
B	Secondary source of supply with a manifold pressure regulator
C	Reserve source of supply with a manifold pressure regulator
D	Single-stage pipeline
E	Double-stage pipeline with line pressure regulator
F	Single-stage pipeline for air for driving surgical tools
G	Single-stage pipeline for medical air
H	Double-stage pipeline for medical air with line pressure regulators
I	Double-stage pipeline for air for driving surgical tools with line pressure regulators
J	Conditioning system
K	Receiver
L	Compressor unit
M	Reserve compressor unit
N	Mixer with receiver and automatic shut-off valve
O	Potential supply source for oxygen pipeline
P	Potential supply source for pipeline for nitrogen for driving surgical tools
Q	Oxygen supply system
R	Nitrogen supply system
S	Drainage trap
T	Bacterial filter
U	Reservoir
V	Vacuum source of supply
W	Vacuum pipeline
X	Supplied via riser or branch

l) test of the quality of air for driving surgical tools produced by air compressor systems (see 12.6.12);

m) test of the quality of medical air produced by proportioning systems (see 12.6.13);

n) test of the quality of oxygen-enriched air produced by oxygen concentrator systems (see 12.6.14);

o) filling with specific gas (see 12.6.15);

p) tests of gas identity (see 12.6.16).

12.5 Requirements for inspections and checks before concealment

12.5.1 Inspection of marking and pipeline supports

Marking shall comply with 10.1. The pipeline supports shall be inspected to verify that they comply with 11.2.

12.5.2 Check for compliance with design specifications

All items shall be shown to comply with the design specifications (e.g. the sizing of the pipelines, location of terminal units, line pressure regulators, if fitted, and shut-off valves).

12.6 Requirements for tests, checks and procedures before use of the system

12.6.1 Tests for leakage and mechanical integrity

One of the following combinations of leakage and mechanical integrity tests shall be carried out:

a) test for mechanical integrity of vacuum pipeline systems (see 12.6.1.1) + test for leakage into the vacuum pipeline systems (see 12.6.1.2) + combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems (after concealment) (see 12.6.1.6);

b) test for mechanical integrity of vacuum pipeline systems (see 12.6.1.1) + test for leakage into the vacuum pipeline systems (see 12.6.1.2) + test for mechanical integrity for compressed medical gas systems (see 12.6.1.3) + test for leakage from the compressed medical gas pipeline systems (see 12.6.1.4);

c) test for mechanical integrity of vacuum pipeline systems (see 12.6.1.1) + test for leakage into the vacuum pipeline systems (see 12.6.1.2) + combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems (before concealment) (see 12.6.1.5) + test for leakage from the compressed medical gas pipeline systems (see 12.6.1.4).

The pressure drop shall be corrected for variations due to temperature according to the ideal gas laws (see Annex E for information).

NOTE Regional or national regulations which apply to requirements for leakage and mechanical integrity can exist.

12.6.1.1 Test for mechanical integrity of vacuum pipeline systems

This test can be carried out before concealment or after concealment and before use of the system. It can be preferable to test sections of the system individually, provided that no section is omitted.

Apply for 5 min a pressure of 500 kPa.

The source of test gas shall be disconnected after initial pressurization.

Check for the integrity of the pipeline distribution system and its components.

12.6.1.2 Test for leakage into the vacuum pipeline systems

This test shall be carried out after concealment and before the use of the system.

With the complete system at nominal distribution pressure, with the source of supply isolated and with all other valves open, the pressure increase in the pipeline shall not exceed 20 kPa after 1 h.

12.6.1.3 Test for mechanical integrity for compressed medical gas pipeline systems

This test shall be carried out before concealment.

Apply for 5 min a pressure of not less than 1,2 times the maximum pressure which could occur under single fault condition in each section of pipeline distribution system.

For double-stage distribution systems, line pressure regulators should not be fitted at this stage of installation and can be replaced by suitable connectors. If so, the test pressure for the complete pipeline should be determined, taking into account the maximum pressure which can be applied to the pipeline downstream of the supply system in single fault condition.

Check for the integrity of the pipeline distribution system and its components.

12.6.1.4 Test for leakage from the compressed medical gas pipeline systems

This test shall be carried out after concealment and before use of the system.

For single-stage pipeline distribution systems, the leakage from the medical gas pipeline system shall be measured from all portion(s) of the system downstream and upstream of each area shut-off valve with the source of test gas disconnected.

For double-stage pipeline distribution systems, the leakage from the medical gas pipeline system shall be measured from all portion(s) of the system downstream and upstream of each line pressure regulator with the source of test gas disconnected.

The means to allow physical isolation of services described in 8.3.5 b) shall be used to isolate the sections upstream and downstream of each area shut-off valve (or each line pressure regulator).

In sections downstream of each area shut-off valve (or each line pressure regulator):

— after a test period of 2 h to 24 h at nominal distribution pressure, the pressure drop shall not exceed 0,4 %/h of the test pressure in portions not including flexible hoses in medical supply units;

— after a test period of 2 h to 24 h at nominal distribution pressure, the pressure drop shall not exceed 0.6 %/h of the test pressure in portions including flexible hoses in medical supply units.

In sections upstream of each area shut-off valve (or each line pressure regulator):

— after a test period of 2 h to 24 h at nominal distribution pressure for single-stage pipeline distribution systems or at nominal supply system pressure for double-stage pipeline distribution systems, the pressure drop shall not exceed 0,025 % of the initial test pressure per hour.

12.6.1.5 Combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems (before concealment)

These tests shall be carried out before concealment.

Apply for 5 min a pressure of not less than 1,2 times the maximum pressure which could occur under single fault condition in each section of pipeline distribution system.

Check for the integrity of the pipeline distribution system and its components.

For double-stage distribution systems, line pressure regulators should not be fitted at this stage of installation and can be replaced by suitable connectors. If so, the test pressure for the complete pipeline should be determined, taking into account the maximum pressure which can be applied to the pipeline downstream of the supply system in single fault condition

At the same test pressure, the pressure drop after a test period of 2 h to 24 h shall be less than 0,025 % of the initial test pressure per hour.

12.6.1.6 Combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems (after concealment)

These tests shall be carried out after concealment and before use of the system.

Mechanical integrity shall be tested for 5 min at a pressure of not less than 1,2 times the maximum pressure which could occur under single fault condition of each section of the pipeline distribution system.

Check for the mechanical integrity of the pipeline distribution system and its components.

The leakage shall then be measured from the whole system with the source of test gas disconnected in accordance with 12.6.1.4.

12.6.2 (*) Tests of area shut-off valves for leakage and closure and checks for correct zoning and correct identification

12.6.2.1 With the system upstream of each closed area shut-off valve under test at nominal distribution pressure, the downstream line depressurized to 100 kPa and all downstream terminal units closed, the pressure increase downstream of each closed area shut-off valve after 15 min shall not exceed 5 kPa.

This test does not apply to vacuum systems.

12.6.2.2 All area shut-off valves shall be checked for correct operation and identification and to show that they control only those terminal units intended by the design.

12.6.3 Test for cross-connection

It shall be proved that there are no cross-connections between pipelines for different gases or vacuum.

12.6.4 Test for obstruction and flow

The pressure change measured at each terminal unit shall not exceed the values specified in Table 4 when the test flowrate specified in Table 4 is taken from each terminal unit or NIST or DISS connector in turn. Each pipeline system shall be at its nominal distribution pressure and connected to the test gas supply.

Table 4 — Maximum allowable pressure change

Pipeline system	Pressure change	Test flowrate
Compressed medical gases other than air or nitrogen for driving surgical tools	−10 %	40 l/min
Air or nitrogen for driving surgical tools	−15 %	350 l/min
Vacuum	+15 kPa	25 l/min
NOTE During this test, the distribution pressure in the vacuum system is subject to change; therefore, an absolute value for the pressure change is appropriate.		

All exhaust pipes (e.g. from pressure-relief valves, terminal units for supply and disposal of air or nitrogen for driving surgical tools) shall be checked for obstruction.

12.6.5 Checks of terminal units and NIST or DISS connectors for mechanical function, gas specificity and identification

12.6.5.1 Mechanical function

This test requires that each terminal unit is complete with its fascia plate.

It shall be demonstrated, for each terminal unit, that the appropriate gas-specific probe can be inserted, captured and released.

If an anti-swivel device is provided, it shall be demonstrated that this retains the probe in the correct orientation.

It shall be demonstrated, for each NIST or DISS connector, that the appropriate nipple can be inserted into the body and secured by the nut.

NOTE This test can be carried out at the same time as the tests described in 12.6.4, 12.6.5.2, 12.6.5.3 and 12.6.16.

12.6.5.2 Gas specificity

It shall be demonstrated for each terminal unit that gas (or vacuum) is released only when the correct probe is inserted and captured, that no other type of probe used in the same healthcare facility can be captured and that no gas (or vacuum) is released when any other type of probe used in the same healthcare facility is inserted.

It shall be demonstrated, for each NIST or DISS connector, that only the correct nipple can be inserted into the body and secured by the nut and that no nipple for other gases (or vacuum) can be inserted and secured.

NOTE This test can be carried out at the same time as the tests described in 12.6.4, 12.6.5.1, 12.6.5.3 and 12.6.16.

12.6.5.3 Identification

All terminal units shall be checked for correct identification and labelling.

NOTE This test can be carried out at the same time as the tests described in 12.6.4, 12.6.5.1, 12.6.5.2 and 12.6.16.

12.6.6 Tests or checks of system performance

Each pipeline system shall be shown to deliver the system design flow at the nominal distribution pressure.

It shall be shown using tests, verification of calculation or other suitable methods that whilst the system is delivering the system design flow, the requirements given in Table 2, 7.2.2, 7.2.3 and 7.2.4 are met at selected terminal units.

12.6.7 (*) Tests of pressure-relief valves

The performance of pressure-relief valves shall be in accordance with 7.2.5 and 7.2.6.

If type-tested and certified pressure-relief valves are fitted, testing after installation is not required.

Evidence shall be provided by the manufacturer.

NOTE Regional or national regulations can require the provision of evidence to a notified body or competent authority upon request.

7.2.2 For compressed medical gases other than air or nitrogen for driving surgical tools, the pressure at any terminal unit shall not be greater than 110 % of the nominal distribution pressure with the system operating at zero flow. The pressure at any terminal unit shall not be less than 90 % of the nominal distribution pressure with the system operating at system design flow and with a flowrate of 40 l/min at that terminal unit.

NOTE 1 System design flow is calculated in accordance with appropriate diversity factors. Examples of diversity factors are given in HTM 02 [25] [26], FD S 90-155 [24] and AS 2896-1998 [16].

NOTE 2 The following factors will contribute to the pressure change: performance of line pressure regulators, pressure drop in the pipeline downstream of the line pressure regulator and pressure drop across the terminal unit.

7.2.3 For air or nitrogen for driving surgical tools, the pressure at any terminal unit shall not be greater than 115 % of the nominal distribution pressure with the system operating at zero flow. The pressure at any terminal unit shall not be less than 85 % of the nominal distribution pressure with the system operating at system design flow and with a flowrate of 350 l/min at that terminal unit.

NOTE 1 System design flow is calculated in accordance with appropriate diversity factors. Examples of diversity factors are given in HTM 02 [25] [26], FD S 90-155 [24] and AS 2896-1998 [16].

NOTE 2 The following factors will contribute to the pressure change: performance of line pressure regulators, pressure drop in the pipeline downstream of the line pressure regulator and pressure drop across the terminal unit.

7.2.4 For vacuum systems, the pressure at any terminal unit shall not be greater than 60 kPa absolute with the system operating at system design flow and with a flowrate of 25 l/min at that terminal unit.

NOTE System design flow is calculated in accordance with appropriate diversity factors. Examples of diversity factors are given in HTM 02 [25], [26], FD S 90-155 [24] and AS 2896-1998 [16].

7.2.5 (*) For compressed medical gases other than air or nitrogen for driving surgical tools, the pressure at any terminal unit shall not exceed 1 000 kPa in a single fault condition of any pressure regulator installed within the system. Means for this purpose (e.g. pressure-relief valves) shall be provided. If fitted, pressure-relief valves shall comply with 5.2.6. Bursting discs shall not be used for this purpose.

Evidence shall be provided by the manufacturer.

NOTE 1 Regional or national regulations can require the provision of evidence to a notified body or competent authority upon request.

NOTE 2 Attention is drawn to regional, national and international standards for pressure-relief valves, e.g. ISO 4126-1 [1].

7.2.6 (*) For air or nitrogen for driving surgical tools, the pressure at any terminal unit shall not exceed 2 000 kPa in a single fault condition of any pressure regulator installed within the system. Means for this purpose (e.g. pressure-relief valves) shall be provided. If fitted, pressure-relief valves shall comply with 5.2.6. Bursting discs shall not be used for this purpose.

Evidence shall be provided by the manufacturer.

NOTE 1 Regional or national regulations can require the provision of evidence to a notified body or competent authority upon request.

NOTE 2 Attention is drawn to regional, national and international standards for pressure-relief valves, e.g. ISO 4126-1 [1].

7.3 Low-pressure hose assemblies and low-pressure flexible connections

7.3.1 Low-pressure hose assemblies, if provided, shall comply with ISO 5359.

NOTE Low-pressure hose assemblies in pipeline distribution systems are normally used for emergency supply of gas to a pipeline or as part of permanently fixed equipment such as booms, pendants and pendant tracks. Low-pressure hose assemblies can be required to electrically isolate terminal units installed close to Nuclear Magnetic Resonance (NMR) systems.

7.3.2 If a low-pressure flexible connection is part of the pipeline, for example when used for isolation of vibration, building movement and relative movement of the pipelines, and is not intended to be replaced during its life, the assembly need not be gas-specific.

7.3.3 If a low-pressure flexible connection is part of a pipeline, it shall be tested in accordance with Clause 12.

7.3.4 If low-pressure flexible connections are provided in the pipeline distribution system, they shall be accessible for inspection and maintenance.

The use of low-pressure hose assemblies and low-pressure flexible connections in the pipeline distribution system should be limited because of the potential hazard arising from their rupture and the subsequent risk of loss of gas supply.

7.4 Double-stage pipeline distribution systems

7.4.1 (*) Alternative arrangements for line pressure regulators are shown in Annex A (Figures A.29 and A.30).

Each bed-space/patient-space shall be supplied from at least two permanently fitted line pressure regulators to ensure continuity of supply. The design flow of the area served shall be supplied by each line pressure regulator.

NOTE 1 These regulators can be combined with the area shut-off valve, see 8.3.

The instructions for use and maintenance shall specify how the two permanently fitted pressure regulators are intended to operate.

NOTE 2 The manufacturer can choose between various means of risk control, e.g. automatic switch-over and alarms, manual switch-over and proper emergency procedures, training and local reserve supplies.

7.4.2 For emergency and maintenance purposes, shut-off valves shall be fitted both upstream and downstream, adjacent to each line pressure regulator.

8 Shut-off valves

8.1 General

8.1.1 Shut-off valves are provided to isolate sections of the pipeline distribution system for maintenance, repair, planned future extensions and to facilitate periodic testing.

The nomenclature for shut-off valves shall be as follows:

a) source shut-off valve;

b) main shut-off valve;

c) riser shut-off valve;

d) branch shut-off valve;

e) area shut-off valve;

f) ring shut-off valve;

g) maintenance shut-off valve;

h) inlet shut-off valve.

NOTE Examples of nomenclature of shut-off valves are given in Annex A.

8.1.2 If not specified, the location of all shut-off valves and the extent of the area served by each area shut-off valve shall be determined by the manufacturer together with the healthcare facility management, using risk analysis procedures in accordance with ISO 14971.

The risk assessment shall also take into account the hazards arising from the possible rupture of low-pressure hose assemblies fitted within any medical supply units.

Consideration should be given to providing a shut-off valve at the point where the pipeline enters a building unless the main, riser or branch shut-off valve is accessible within the building.

8.1.3 All shut-off valves shall be identified by indicating

a) the gas or vacuum service name or symbol, or

b) the risers, branches or areas controlled.

This identification shall be secured to the valve, valve box or the pipeline and be readily visible at the valve site.

8.1.4 For all shut-off valves in a medical gas pipeline system, it shall be apparent by observation whether the valve is open or closed.

8.1.5 A source shut-off valve shall be provided downstream (upstream for vacuum) of each source of supply.

8.1.6 An inlet shut-off valve shall be provided on the pipeline immediately upstream of the maintenance supply assembly, if provided.

8.1.7 Shut-off valves shall be lockable in the open and closed positions; shut-off valves which cannot be locked in the open or closed position shall be protected from operation by unauthorized personnel.

8.2 Service shut-off valves

8.2.1 Typical uses of service shut-off valves are

a) as shut-off riser valves,

b) as shut-off branch valves,

c) as shut-off maintenance valves, or

d) as shut-off ring valves.

8.2.2 Service shut-off valves shall be used only by the authorized personnel and should not be accessible to unauthorized persons.

8.2.3 Each riser shall be provided with a shut-off valve adjacent to the connection to the main line.

8.2.4 Each branch shall be provided with a shut-off valve adjacent to the connection to the riser or main line

8.3 Area shut-off valves

8.3.1 All terminal units in the pipeline system other than those provided only for emergency, system test purposes or maintenance of components (e.g. line pressure regulators) shall be downstream of an area shut-off valve (upstream for vacuum). An area shut-off valve shall be provided in each gas and vacuum pipeline serving each operating theatre, general ward area and all other departments.

8.3.2 Area shut-off valves shall be located on the same floor as the terminal units they serve

8.3.3 Area shut-off valves shall be used to isolate areas within healthcare facilities for maintenance and emergency purposes. Their operation, in the latter case, should be included as part of the emergency disaster plan.

8.3.4 Area shut-off valves shall be housed in boxes with covers or doors. The boxes shall be labelled with the following or similar wording:

CAUTION — Do not close valve(s) except in emergency.

8.3.5 Each box shall contain the following:

a) area shut-off valve(s) for one or more gases;

b) except for vacuum systems, means to allow physical isolation of the service(s). These means shall be clearly visible when deployed. A closed valve shall not be considered an adequate physical isolation when modifications are carried out to existing systems.

8.3.6 Each box shall be vented to the room to prevent accumulation of gas and shall have a cover or door which can be secured in the closed position. The cover or door shall allow quick access in case of emergency.

8.3.7 All boxes shall be located within normal hand height and shall be visible and accessible at all times. Consideration shall be given to prevent access by unauthorized personnel, especially in psychiatric or paediatric units.

8.3.8 Except for pipelines for vacuum and for air or nitrogen for driving surgical tools, an emergency and maintenance inlet point shall be provided downstream of each area shut-off valve. The emergency and maintenance inlet point shall be gas-specific (either a NIST or DISS body or the socket of a terminal unit). The dimensions of the inlet point shall take into account the flow required during emergency and maintenance activities. The emergency and maintenance inlet point can be located within the box containing the area shut-off valve.

8.3.9 Except for

- sensors or indicators (e.g. for pressure and flow),
- emergency and maintenance inlet points,
- means to allow physical isolation of the service,
- maintenance shut-off valves (if fitted),
- operator-adjustable low-pressure regulators for air or nitrogen for driving surgical tools (see ISO 10524-4 [14]),

no components shall be installed between an area shut-off valve and the terminal units.

9 Terminal units, gas-specific connectors, medical supply units, pressure regulators and pressure gauges

9.1 Terminal units shall comply with ISO 9170-1.

9.2 Gas-specific connectors shall be either the gas-specific connection point of a terminal unit complying with ISO 9170-1 or the body of a connector complying with ISO 5359.

9.3 Medical supply units (e.g. ceiling pendants, bedhead units, booms) shall comply with ISO 11197.

9.4 Manifold and line pressure regulators shall comply with ISO 10524-2.

9.5 Pressure gauges shall comply with the requirements given in ISO 10524-2.

5.5.3.2 A supply system with proportioning unit(s) shall comprise at least three sources of supply, at least one of which shall be a proportioning unit. The supply system shall be such that the system design flow can be supplied with any two sources of supply out of service.

NOTE 1 A supply system with proportioning units typically consists of one of the following:

a) sources of oxygen and nitrogen, one proportioning unit and two banks of cylinders or cylinder bundles;

b) sources of oxygen and nitrogen, two proportioning units and one bank of cylinders or cylinder bundles.

NOTE 2 A proportioning unit typically comprises the following:

a) a mixer with a process control analyser;

b) an automatic shut-off valve controlled by the pressure of the supply gas, a pressure regulator and a non-return valve for each of the supply gases;

c) a medical air receiver fitted with a pressure-relief valve and a pressure gauge;

d) a quality control analyser connected to the receiver;

e) an automatic shut-off valve fitted downstream of the receiver.

5.5.3.3 The sources of oxygen and nitrogen for proportioning systems shall conform to the requirements of 5.2 and 5.4 and can be the same sources as those supplying the medical gas pipelines separately. Means shall be provided to prevent cross-contamination between gases supplying the proportioning unit.

5.5.3.4 A proportioning system shall operate automatically.

The oxygen concentration of the mixture shall be analysed continuously by two independent oxygen-analysing systems. At least one oxygen-analysing system shall be fitted on or downstream of the receiver. Recording capability for oxygen concentration shall be provided.

If the oxygen concentration of the mixture or the pressure supplied to the pipeline distribution system goes out of specification, an alarm shall be activated and the proportioning system shall be automatically isolated by closing the controlled shut-off valve fitted downstream of the receiver. The secondary source of supply shall then automatically supply the pipeline. The system shall be arranged so that manual intervention is necessary to correct the composition of the mixture before reconnecting the proportioning system to the pipeline system.

5.5.3.5 A proportioning system shall be capable of supplying a mixture of the required composition over the entire range of specified flowrates.

5.5.3.6 A proportioning system shall include means for verifying the calibration of the analysing system(s) by reference to mixture(s) of known composition.

5.5.3.7 A sample port with a shut-off valve shall be provided immediately upstream of the main shut-off valve(s).

5.6 Supply systems with oxygen concentrator(s)

5.6.1 Where national or regional regulations permit the use of oxygen-enriched air, the supply systems with oxygen concentrator(s) shall comply with ISO 10083.

5.6.2 If not specified by regional or national regulations, the specification for oxygen-enriched air shall comply with ISO 10083.

NOTE Regional or national regulations applying to oxygen-enriched air can exist.

5.7 Supply systems for vacuum

5.7.1 A supply system for vacuum shall comprise at least three sources of supply, one reservoir, two parallel bacterial filters and one drainage trap. A source of supply typically comprises one or more vacuum pumps.

5.7.2 Where the three sources of supply consist of three separate pumps, each pump shall be capable of supplying the system design flow to ensure continuity of supply.

5.7.3 Where the supply system for vacuum consists of more than three pumps, which can be switched between the different sources of supply to provide adequate capacity, these shall be arranged so that during maintenance on any pump or system component and during a subsequent single fault condition on any component of the system (e.g. control system), the remaining pumps and components shall be capable of supplying the system design flow to ensure continuity of supply.

5.7.4 Each pump shall have a control circuit arranged so that shutting off, or failure, of one pump will not affect the operation of other pumps. The controls shall be arranged so that all the pumps supply the system in turn or simultaneously. This requirement shall be met in normal condition and in single fault condition of the control system.

5.7.5 All supply systems for vacuum shall comply with 5.2.2.1. All sources of supply shall be connected to the emergency power supply.

5.7.6 Reservoirs shall comply with appropriate regional or national standards.

5.7.7 Each reservoir shall be fitted with maintenance shut-off valve(s), a drain valve and a vacuum gauge. If only one reservoir or one drainage trap is fitted, means of bypass shall be provided.

5.7.8 The exhaust(s) from the vacuum pumps shall be piped to the outside and shall be provided with means to prevent the ingress of, for example, insects, debris and water. The exhaust(s) shall be located remote from any air intakes, doors, windows or other openings in buildings. Consideration should be given to the potential effects of prevailing winds on the location of exhaust(s).

5.7.9 The exhaust line shall be provided with a drain at its lowest point.

5.7.10 If necessary, means shall be provided to prevent the transmission of vibration from the vacuum pumps to the pipeline.

5.7.11 Each bacterial filter shall be capable of passing the system design flow at normal operating condition.

5.7.12 Vacuum supply systems complying with this part of ISO 7396 shall not be used as AGS power devices (see ISO 7396-2 [5]).

5.8 Location of supply systems

Gas and non-cryogenic liquid cylinder supply systems shall not be located in the same room as medical air compressors, oxygen concentrators or vacuum supply systems.

The location of supply systems shall take into account potential hazards (e.g. contamination and fires) arising from the location of other equipment or other supply systems within the same room.

These locations shall be provided with drainage facilities.

(*) The ambient temperature in rooms for supply systems shall be in the range of 10 °C to 40 °C.

Where the medical air supply system consists of more than two conditioning units which can be switched between the different sources of supply to provide adequate capacity, these shall be arranged so that during maintenance on any conditioning unit or system component and during a subsequent single fault condition on any component of the system (e.g. control system), the remaining conditioning unit(s) and components shall be capable of supplying the system design flow to ensure continuity of supply of the appropriate product quality. At least one dew-point alarm sensor shall be fitted to the pipeline system downstream of all conditioning units. Recording capability of the water vapour content should be provided.

Each compressor unit shall have an automatic means to prevent backflow through off-cycle units and a shut-off valve to isolate it from the pipeline system and other compressors.

NOTE 1 A supply system with compressors for medical air typically comprises one of the following:

a) one compressor unit with one receiver, one conditioning unit and two banks of cylinders or cylinder bundles;

b) two compressor units with two receivers, two conditioning units and one bank of cylinders or cylinder bundles;

c) three compressor units with two receivers and two conditioning units.

NOTE 2 A compressor unit for medical air typically comprises the following:

a) an inlet filter;

b) one or more compressors;

c) an after-cooler with shut-off valve and automatic drain;

d) an oil separator with shut-off valve and automatic drain.

NOTE 3 A conditioning unit for medical air typically comprises the following:

a) a dryer with shut-off valves and automatic drain;

b) an adsorber, a catalyst and filter(s) as required to remove contaminants;

c) a dew-point sensor fitted with an alarm and display, connected to the pipeline system downstream of all conditioning units.

5.5.2.5 If an independent supply system with compressors for air for driving surgical tools is provided, it shall comprise at least two sources of supply, at least one of which shall be a compressor unit.

At least one dew-point alarm sensor shall be fitted to the pipeline system downstream of all conditioning units.

NOTE 1 A supply system with compressors for air for driving surgical tools typically comprises one of the following:

a) one compressor unit with one receiver, one conditioning unit and one bank of cylinders or cylinder bundles;

b) two compressor units with one or more receivers fitted with a means of bypass and two conditioning units.

NOTE 2 A compressor unit for air for driving surgical tools typically comprises the following:

a) an inlet filter;

b) one or more compressors;

c) an after-cooler with shut-off valve and automatic drain;

d) an oil separator with shut-off valve and automatic drain.

NOTE 3 A conditioning unit for air for driving surgical tools typically comprises the following:

a) a dryer with shut-off valves and automatic drain;

b) filter(s) as required;

c) a dew-point sensor fitted with an alarm and display, connected to the pipeline system downstream of all conditioning units

5.5.2.6 Receivers shall

a) comply with EN 286-1 or equivalent national standards, and

b) be fitted with shut-off valve(s), an automatic drain, a pressure gauge and a pressure-relief valve.

5.5.2.7 Each group of receivers shall be arranged so as to allow each receiver in that group to be maintained separately.

5.5.2.8 If two or more conditioning units are fitted, they shall allow the components to be maintained separately.

5.5.2.9 A sample port with a shut-off valve shall be provided immediately downstream of the conditioning system(s).

5.5.2.10 When more than one compressor unit is provided, each compressor shall have a control circuit arranged so that shutting off, or failure, of one compressor will not affect the operation of other compressor(s). The automatic controls for multiple compressors shall be arranged so that all the units supply the system in turn or simultaneously. This requirement shall be met in normal condition and in single fault condition. Each receiver or group of receivers shall be fitted with a means of pressure control, e.g. pressure switch(es) or pressure transducer(s).

5.5.2.11 The intake of the ambient air for compressors shall be located where there is minimal contamination from internal combustion engine exhaust, vehicle parking, access areas, hospital waste and disposal systems, vacuum system exhausts, vents from medical gas pipeline systems, anaesthetic gas scavenging systems, ventilation system discharges, chimney outlets and other sources of contamination. The inlet shall be provided with means to prevent the ingress of, for example, insects, debris and water on the location of the intake(s). Consideration should be given to the potential effects of prevailing winds on the location of the intake(s) which should be remote from chimney outlets.

5.5.2.12 A supply system with compressors for medical air intended to supply a single-stage pipeline distribution system shall include two permanently fitted pressure regulators. The design flow of the pipeline distribution system shall be supplied by each pressure regulator.

The instructions for use and maintenance shall specify how the two permanently fitted pressure regulators are intended to operate.

5.5.2.13 If necessary, means shall be provided to prevent transmission of vibration between each compressor and the pipeline.

5.5.3 Supply systems with proportioning unit(s)

5.5.3.1 Regional or national regulations applying to medical air produced by proportioning unit(s) can exist. Where such regulations do not exist, medical air shall comply with the following:

a) oxygen concentration	$\geq$ 19,95 % (volume fraction) and $\leq$ 23,63 % (volume fraction)
b) water vapour content	$\leq$ 67 ml/m^3

NOTE These values are taken from the European Pharmacopoeia 2005

3.51

supply pressure regulator

pressure regulator fitted within a source of supply and intended to regulate the pressure supplied to the line pressure regulator(s)

NOTE For a source of supply with cylinders or cylinder bundles, this is referred to as the manifold pressure regulator.

3.52

supply system

assembly which supplies the pipeline distribution system and which includes all sources of supply

3.53

system design flow

flow calculated from the maximum flow requirement of the healthcare facility and corrected by the diversity factor(s)

3.54

terminal unit

outlet assembly (inlet for vacuum) in a medical gas pipeline system at which the operator makes connections and disconnections

3.55

vacuum supply system

supply system equipped with vacuum pumps designed to provide a flow at negative pressure

4 General requirements

4.1 (*) Safety

Medical gas pipeline systems shall, when installed, extended, modified, commissioned, operated and maintained according to the instructions of the manufacturer, present no risks that are not reduced to an acceptable level using risk management procedures in accordance with ISO 14971 and which are connected with their intended application, in normal condition and in single fault condition.

NOTE 1 A situation in which a fault is not detected is considered a normal condition. Fault conditions/hazardous situations can remain undetected over a period of time and as a consequence can lead to an unacceptable risk. In that case, a subsequent detected fault condition needs to be considered as a single fault condition. Specific risk control measures to deal with such situations need to be determined within the risk management process.

NOTE 2 Typical safety hazards (including discontinuity of supply, incorrect pressure and/or flow, wrong gas supply, wrong gas composition, contamination, leakage, fire) are listed in Annex F.

4.2 (*) Alternative construction

Pipeline installations and components, or parts thereof, using materials or having forms of construction different from those detailed in this part of ISO 7396, shall be presumed to be in compliance with the safety objectives of this part of ISO 7396 if it can be demonstrated that an equivalent degree of safety is obtained (i.e. compliance with requirements presumes that risks have been mitigated to acceptable levels) unless objective evidence to the contrary becomes available.

NOTE 1 Objective evidence can be obtained by post-market surveillance.

Evidence of an equivalent degree of safety shall be provided by the manufacturer.

NOTE 2 Regional or national regulations can require the provision of evidence to a competent authority or a conformity assessment body, e.g. to a notified body in the European Economic Area (EEA) upon request.

4.3 Materials

4.3.1 (*) The manufacturer shall disclose, upon request, evidence of the corrosion resistance of the materials used for pipes and fittings.

NOTE Corrosion resistance includes resistance against the influence of moisture and the surrounding materials.

4.3.2 (*) The manufacturer shall disclose, upon request, evidence that the materials used in components of the medical gas pipeline system which come into contact with the actual gas shall be compatible with the actual gas and oxygen under normal and single fault condition. If lubricants are used, except within air compressors and vacuum pumps, they shall be compatible with oxygen during normal and single fault condition of the pipeline system.

Evidence shall be provided by the manufacturer.

NOTE 1 Criteria for the selection of metallic and non-metallic materials are given in ISO 15001.

NOTE 2 Regional or national regulations can require the provision of evidence to a notified body or competent authority upon request.

NOTE 3 Compatibility with oxygen involves both combustibility and ease of ignition. Materials which burn in air will burn violently in pure oxygen. Many materials which do not burn in air will do so in pure oxygen, particularly under pressure. Similarly, materials which can be ignited in air require less energy to ignite in oxygen. Many such materials can be ignited by friction at a valve seat or by adiabatic compression produced when oxygen at high pressure is rapidly introduced into a system initially at low pressure.

4.3.3 The specific hazards of toxic products from combustion or decomposition of non-metallic materials (including lubricants, if used) and potential contaminants shall be addressed. Some potential products of combustion and/or decomposition for some commonly available non-metallic materials are listed in Table D.7 of ISO 15001:2003.

NOTE Typical "oxygen-compatible" lubricants can generate toxic products on combustion or decomposition.

Annex E of ISO 15001:2003 gives details of suitable test and quantitative analysis methods for the products of combustion of non-metallic materials. Data from such tests shall be considered in any risk evaluation.

4.3.4 (*) Components of systems which can be exposed to cylinder pressure in normal or single fault condition shall function according to their specifications after being exposed to a pressure of 1,5 times the cylinder working pressure for 5 min.

Evidence shall be provided by the manufacturer.

NOTE Regional or national regulations can require the provision of evidence to a notified body or competent authority upon request.

4.3.5 (*) Components of systems which can be exposed to cylinder pressure in normal or single fault condition shall not ignite or show internal scorching damage when submitted to oxygen pressure shocks. The test for resistance to ignition shall be in accordance with ISO 10524-2.

Evidence shall be provided by the manufacturer.

NOTE Regional or national regulations can require the provision of evidence to a notified body or competent authority upon request.

4.3.6 (*) Except for low-pressure hose assemblies and low-pressure flexible connections, metallic materials shall be used for compressed medical gas pipelines. If copper pipes of $\leqslant$ 108 mm diameter are used for pipelines, they shall comply with EN 13348 or equivalent national standards. Copper pipes of > 108 mm diameter and pipes of materials other than copper which are used for compressed medical gases shall comply with the cleanliness requirements of EN 13348 or equivalent national standards. If non-metallic materials are used for vacuum pipelines, these materials shall be compatible with the potential contaminants that can be present in the vacuum system.

Introduction

Many healthcare facilities use pipeline systems to deliver medical gases and to provide vacuum to areas where they are used in patient care or to power equipment such as ventilators and surgical tools.

This part of ISO 7396 specifies requirements for pipeline systems for compressed medical gases, gases for driving surgical tools and vacuum. It is intended for use by those persons involved in the design, construction, inspection and operation of healthcare facilities treating human beings. Those persons involved in the design, manufacture and testing of equipment intended to be connected to pipeline systems should also be aware of the contents of this document.

This part of ISO 7396 seeks to ensure that medical gas pipelines contain only the specific gas (or vacuum) intended to be supplied. For this reason, gas-specific components are used for terminal units and for other connectors which are intended to be used by the operator. In addition, each system is tested and certified to contain only the specific gas (or vacuum).

The objectives of this part of ISO 7396 are to ensure the following:

a) non-interchangeability between different pipeline systems by design;

b) continuous supply of gases and vacuum at specified pressures by providing appropriate sources;

c) use of suitable materials;

d) cleanliness of components;

e) correct installation;

f) provision of monitoring and alarm systems;

g) correct marking of the pipeline system;

h) testing, commissioning and certification;

i) purity of the gases delivered by the pipeline system;

j) correct operational management.

Annex H contains rationale statements for some of the requirements of this part of ISO 7396. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this part of ISO 7396. The clauses and subclauses marked with (*) after their number have a corresponding rationale contained in Annex H.

Evidence shall be provided by the manufacturer.

NOTE 1 Regional or national regulations can require the provision of evidence to a notified body or competent authority upon request.

NOTE 2 Copper pipes of > 108 mm diameter are not covered by EN 13348.

NOTE 3 Copper is the preferred material for all medical gas pipelines, including vacuum.

4.3.7 Pipeline components which come in contact with the actual gas shall be supplied in a clean condition (see 4.3.8) and protected from contamination prior to, and during, installation.

4.3.8 **(*)** Components of the system other than pipes, which are liable to come in contact with the actual gas, shall meet the cleanliness requirements of ISO 15001.

NOTE Examples of cleaning procedures are described in ISO 15001.

4.3.9 Materials for pipelines and components installed in the vicinity of strong magnetic or electromagnetic fields [e.g. Nuclear Magnetic Resonance (NMR), Magnetic Resonance Imaging (MRI)] shall be selected for compatibility with these applications.

4.4 System design

4.4.1 General

The number of terminal units per bed-space/work-space and their location in each department or area of the healthcare facility, together with the corresponding flowrates required and the diversity factors, shall be defined by the management of the healthcare facility in consultation with the system manufacturer.

NOTE 1 Typical examples of locations of terminal units, flow requirements and diversity factors are given in HTM 02 [25], [26], FD S 90-155 [24], AS 2896-1998 [16] and SIS HB 370 [30].

The sizing of the pipelines shall take into account the potential hazards arising from high gas velocity.

NOTE 2 Examples of maximum recommended gas velocity are given in FD S 90-155 [24] and SIS HB 370 [30].

4.4.2 Extensions and modifications of existing pipeline systems

Extensions and modifications of existing pipeline systems shall comply with the relevant requirements of this part of ISO 7396. In addition, the following requirements apply:

a) the flow capacity of the supply system shall continue to meet the flow requirements of the extended or modified pipeline system. For this purpose, the existing supply system might need to be upgraded;

b) the flow and pressure drop characteristics of the existing pipeline distribution system shall continue to meet at least the original design specifications;

c) the flow and pressure drop characteristics of the extension or modification to the existing pipeline distribution system shall meet the requirements of 7.2. For this purpose, modifications of the existing pipeline distribution system might be needed.

5 Supply systems

5.1 System components

5.1.1 Except for air or nitrogen for driving surgical tools, each supply system shall comprise at least three independent sources of supply which can be a combination of the following:

a) gas in cylinders or cylinder bundles;

b) non-cryogenic liquid in cylinders;

c) cryogenic or non-cryogenic liquid in mobile vessels;

d) cryogenic or non-cryogenic liquid in stationary vessels;

e) an air compressor system;

f) a proportioning system;

g) an oxygen concentrator system (see ISO 10083).

5.1.2 A supply system for air or nitrogen for driving surgical tools shall comprise at least two sources of supply.

5.1.3 A supply system for vacuum shall consist of at least three vacuum pumps.

5.1.4 Schematic representations of typical supply systems are given in Annex A (Figures A.1 to A.27).

5.2 General requirements

5.2.1 Capacity and storage

The capacity and storage of any supply system shall be based on the estimated usage and frequency of delivery. The location and the capacity of the primary, secondary and reserve sources of supply of all supply systems and the number of full cylinders held in storage, as defined by the management of the healthcare facility in consultation with the gas supplier using risk management principles, shall be taken into account by the system manufacturer. Appropriate undercover storage facilities for cylinders should be provided to ensure that the cylinders are maintained in a safe, secured and clean condition.

5.2.2 Continuity of supply

5.2.2.1 The supply systems for compressed medical gases and vacuum shall be designed to achieve continuity of system design flow at a distribution pressure complying with 7.2 in normal condition and in single fault condition.

NOTE Loss of mains electrical power or water supply is a single fault condition. A fault in control equipment is a single fault condition.

In order to achieve this objective,

a) the supply systems for compressed medical gases and vacuum shall comprise at least three sources of supply, i.e. primary source of supply, secondary source of supply and reserve source of supply, and

b) the layout and the location of the pipelines shall reduce the risk of mechanical damage of the pipeline to an acceptable level.

Failure of the pipeline is considered a catastrophic event and not a single fault condition, and should be managed in accordance with the emergency procedure (see Annex G).

Indian Standard
MEDICAL GAS PIPELINE SYSTEMS
PART 1 PIPELINE SYSTEMS FOR COMPRESSED MEDICAL GASES AND VACUUM

1 Scope

This part of ISO 7396 specifies requirements for design, installation, function, performance, documentation, testing and commissioning of pipeline systems for compressed medical gases, gases for driving surgical tools and vacuum in healthcare facilities to ensure continuous delivery of the correct gas and the provision of vacuum from the pipeline system. It includes requirements for supply systems, pipeline distribution systems, control systems, monitoring and alarm systems and non-interchangeability between components of different gas systems.

This part of ISO 7396 is applicable to:

a) pipeline systems for the following medical gases:

— oxygen;

— nitrous oxide;

— medical air;

— carbon dioxide;

— oxygen/nitrous oxide mixtures (see Note 1);

b) pipeline systems for the following gases:

— (*) oxygen-enriched air;

— air for driving surgical tools;

— nitrogen for driving surgical tools;

c) pipeline systems for vacuum.

This part of ISO 7396 also applies to:

— extensions of existing pipeline distribution systems;

— modifications of existing pipeline distribution systems;

— modifications or replacement of supply systems or sources of supply.

NOTE 1 Regional or national regulations can prohibit the distribution of oxygen/nitrous oxide mixtures in medical gas pipeline systems.

(*) NOTE 2 EN 14931 [23] defines additional or alternative requirements for the specific application, in particular for flows and pressures of compressed air required to pressurize the hyperbaric chambers and to drive other connected services and of oxygen and other treatment gases administered to patients.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3746, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane*

ISO 5359, *Low-pressure hose assemblies for use with medical gases*

ISO 8573-1:2001, *Compressed air — Part 1: Contaminants and purity classes*

ISO 9170-1, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 10083, *Oxygen concentrator supply systems for use with medical gas pipeline systems*

ISO 10524-2, *Pressure regulators for use with medical gases — Part 2: Manifold and line pressure regulators*

ISO 11197, *Medical supply units*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15001:2003, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

ISO 21969, *High-pressure flexible connections for use with medical gas systems*

IEC 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for safety — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

EN 286-1, *Simple unfired pressure vessels designed to contain air or nitrogen — Part 1: Pressure vessels for general purposes*

EN 1041, *Information supplied by the manufacturer with medical devices*

EN 13348, *Copper and copper alloys — Seamless, round copper tubes for medical gases or vacuum*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
air compressor system
supply system with compressor(s) designed to provide medical air or air for driving surgical tools or both

3.2
air for driving surgical tools
natural or synthetic mixture of gases, mainly composed of oxygen and nitrogen in specified proportions, with defined limits for the concentration of contaminants, supplied by a medical gas pipeline system and intended for driving surgical tools

NOTE Different names or symbols are used for air for driving surgical tools, such as instrument air, surgical air, air motor, air - 700 and air - 800.

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This Indian Standard has been developed from Doc No.: MHR 11 (040).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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PRINTED BY THE GENERAL MANAGER, GOVT. OF INDIA PRESS, NASHIK-422 006